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7 CFR Part 205
National Organic Program; Proposed Rule

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Docket Number: TMD–00–02–PR2]

RIN 0581–AA40

National Organic Program

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish a National Organic Program (NOP or program) under the direction of the Agricultural Marketing Service (AMS), an arm of the United States Department of Agriculture (USDA). This national program is intended to facilitate interstate commerce and marketing of fresh and processed food that is organically produced and to assure consumers that such products meet consistent, uniform standards. This program will establish national standards for the production and handling of organically produced products, including a National List of substances approved and prohibited for use in organic production and handling. This proposal will establish a national-level accreditation program to be administered by AMS for State officials and private persons who want to be accredited as certifying agents. Under the program, certifying agents will certify production and handling operations in compliance with the requirements of this regulation and initiate compliance actions to enforce program requirements. The proposal includes requirements for labeling products as organic and containing organic ingredients. The rule also provides for importation of organic agricultural products from foreign programs determined to have equivalent organic program requirements. The program is proposed under the Organic Foods Production Act of 1990, as amended.

DATES: Comments must be submitted on or before June 12, 2000.

ADDRESSES: Interested persons are invited to submit written comments on this proposal to: Keith Jones, Program Manager, National Organic Program, USDA–AMS–TMP–NOP, Room 2945–So., Ag Stop 0275, PO Box 96456, Washington, DC 20090–6456. Comments also may be sent by fax to (703) 365–0760 or filed via the Internet through the National Organic Program's homepage at: http://www.ams.usda.gov/nop. Written comments to this proposed rule submitted by regular mail and faxed comments should be identified with docket number TMD–00–02-PR. To facilitate the timely scanning and posting of comments to the NOP homepage, multiple page comments submitted by regular mail should not be stapled or clipped. Commenters should identify the topic and section number of this proposal to which the comment refers.

It is our intention to have all comments to this proposal, whether mailed, faxed, or submitted via the Internet, available for viewing on the NOP homepage at http://www.ams.usda.gov/nop in a timely manner. Comments submitted in response to this proposal will be available for viewing at USDA–AMS, Transportation and Marketing, Room 2945–South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 12:00 p.m. and from 1:00 p.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposal are requested to make an appointment in advance by calling (202) 720–3252.

FOR FURTHER INFORMATION CONTACT: Richard Mathews, Senior Agricultural Marketing Specialist, USDA–AMS–TM–NOP, Room 2510–So., PO Box 96456, Washington, DC 20090–6456; Telephone: (202) 205–7806; Fax: (202) 205–7808.

SUPPLEMENTARY INFORMATION:

Background of the National Organic Program

To address problems created by inconsistent organic standards, the organic industry attempted to establish a national voluntary organic certification program in the late 1980's. However, that effort failed to develop a consensus on needed organic standards. Congress was then petitioned by an organic industry trade association to establish a mandatory national organic program, resulting in the Organic Foods Production Act of 1990 (the Act). Congress passed the Act to: (1) Establish national standards governing the marketing of certain agricultural products as organically produced products; (2) assure consumers that organically produced products meet a consistent standard; and (3) facilitate commerce in fresh and processed food that is organically produced. This proposal is designed to implement the Act.

To help readers better understand this proposal, we have provided answers to some frequently asked questions about the proposed rule, including some of the issues most commonly raised in public comments.

Is this the final word on National organic standards?

No. This is only a proposed rule. It is important that you take the time to read it carefully and write to USDA to give us your recommendations, being as specific as you can. Your comments are due by June 12, 2000.

Your comments do matter. On December 16, 1997, the first proposed rule was published in the **Federal Register**, and 275,603 people wrote to us to explain why and how the rule should be rewritten, the largest public response to a proposed rule in USDA history. Then, in the October 24, 1998 **Federal Register**, we asked for public comment on issues concerning livestock confinement, medications, and the authority of certifying agents, and 10,817 people wrote to us. As you read through this document, you will get a sense of what these comments said because in each section we briefly summarize the relevant comments and provide our response to them.

We expect to publish a final rule later this year, once we know what you think about this proposal. The final rule will have, as proposed here, an implementation phase-in period so farmers and processors won't have to change overnight.

Has there been citizen input on this proposal beyond public comments?

Yes. The National Organic Standards Board (NOSB) is a 15-member citizen board that advises the Secretary on all aspects of the National Organic Program and has special responsibility for development of the National List. Established by law in 1990, the NOSB includes 3 environmental representatives, 3 consumer representatives, 4 organic farmers/ranchers, 2 organic processors, 1 retailer, 1 scientist, and 1 certifying agent. Currently, the NOSB comprises 14 members. The 15th member, an accredited certifying agent, would be appointed after certifying agents are accredited by the Secretary. Since the first NOSB was appointed in 1993, the Board has held 19 public meetings, including one public teleconference, crisscrossing the country to hear from the public before making recommendations to the Secretary on national standards. The vast majority of commenters on the first proposed rule urged the Secretary to rewrite the proposal in line with NOSB recommendations—and this is what we have done. More information on NOSB

members, meeting minutes, and a side-by-side comparison of this proposal with NOSB recommendations can be found at www.ams.nop/gov.

In addition, to be consistent with OMB Circular No, A–119, which directs agencies to use voluntary consensus standards, USDA considered adoption of the *American Organic Standards, Guidelines for the Organic Industry* as a voluntary consensus standard for use in the National Organic Program. In October 1999, the Organic Trade Association published the American Organic Standards (AOS). The AOS standards were developed over several months with two opportunities for comment from interested parties. The introduction states that the standards are written as an up-to-date compilation and codification of organic standards and certification procedures, as they are understood and applies in the United States. Organic Trade Association members are expected to follow the guidelines.

USDA has determined that it would be impractical to use the American Organic Standards in lieu of USDA developed standards for the following reasons: (1) Not all participants in the organic industry elected to participate in developing the AOS; (2) the AOS are new to the industry so there has not been sufficient time for the industry to assess their effectiveness, and (3) some certifying agents disagree with portions of the AOS.

Why do we need national standards for organic food?

National standards for organic food production are designed to bring about greater uniformity in the production, manufacture, and marketing of organic products. In the absence of a national standard, 49 State and private organizations have established individual programs and standards for certifying organic agricultural products. The lack of consistency between these standards has created problems for farmers and handlers of organic products, particularly if they want to sell their products in multiple States with different standards. Lack of a nationwide standard has also created confusion for consumers, who may be uncertain what it really means when a food product is called ''organic.''

With a national standard, consumers across the country can go into any store and have full confidence that any food product labeled ''organic'' meets a strict, consistent standard no matter where it was made. Use of the word, ''organic,'' on the label of any product that does not meet the standard is strictly prohibited.

Consumers will have that confidence, because this proposal requires for the first time that all organic operations be certified by USDA-approved certifying agents. Up to now, certification has been optional; some farmers choose not to be certified at all, and others are certified by State or private certifiers using different standards. It can be hard for consumers to know if a product has been certified, or, if it has, to what standard. Under this proposal, all organic operations, except for the very smallest, would be certified to the same standard. And all products labeled as ''organic'' would have to comply with the production and handling standards in this rule.

Consumers can also look for the USDA organic seal, which can only be used on products that have been certified by USDA-approved certifying agents. This seal assures consumers that the maker of the product is part of a rigorous certification program and has been thoroughly reviewed by professional inspectors trained in organic agriculture.

National standards will also bring greater predictability for producers of organic foods. There will be no confusion about whether a product satisfies the particular standard of any State, for example, because all organic foods will meet the same standards.

Finally, a national standard for organic food will help our farmers and manufacturers sell organic products in other countries. The lack of a consistent national organic program has limited access to important markets in other countries because of the confusion created by multiple, independent standards. A strong national standard will help to ensure buyers in other countries that all U.S. organic products meet the same standards.

How can I tell how much organic food is in a product?

This proposal sets strict labeling standards based on the percentage of organic content. If a product is 100 percent organic, it can, of course, be labeled as such. A product that is at least 95 percent organic can be described as, for example, ''organic cereal.'' If a cereal, for example, contains between 50 and 95 percent organic content, it can be described as ''cereal made with organic ingredients,'' and up to three organic ingredients can be listed. Finally, if the food contains less than 50 percent organic content, the term, ''organic,'' may only appear on the ingredient information panel. These four new labeling categories will provide consumers with much greater information than they have today. [Labeling is covered in subpart D.]

What is the National List?

The National List of Allowed and Prohibited Substances (known as the National List) identifies specific substances that may or may not be used in organic production and handling operations. The National List is developed by the NOSB, through consultation with outside experts, and forwarded to the Secretary for approval. The list identifies those synthetic substances, which would otherwise be prohibited, that may be used in organic production based on the recommendations of the NOSB. Only those synthetic substances found on the National List may be used. The National List also identifies those natural substances that may not be used in organic production, as determined by the Secretary based on the NOSB recommendations.

The first proposal included some substances on the National List that were not recommended by the NOSB. This proposal contains no substances on the approved list that were not found in the NOSB recommendations.

This proposal also includes restrictions or other conditions on the use of allowed substances, also known as ''annotations,'' as recommended by the NOSB. Such annotations have been used by existing State and private certification programs to further ensure that allowed substances are used in a manner that is consistent with organic production. (The National List is covered in subpart G, §§ 205.600 through 205.607.)

Does this proposal prohibit use of genetic engineering in organic production?

Yes. This proposal prohibits the use of genetic engineering (included in the broad definition of ''excluded methods'' in this proposal, based on the definition recommended by the National Organic Standards Board) in the production of all foods and ingredients that carry the organic label.

275,603 commenters on the first proposal nearly universally opposed the use of this technology in organic production systems. Based on this overwhelming public opposition, this proposal prohibits its use in the production of all organic foods even though there is no current scientific evidence that use of excluded methods presents unacceptable risks to the environment or human health. While these methods have been approved for use in general agricultural production and may offer certain benefits for the

environment and human health, consumers have made clear their strong opposition to their use in organically grown food. Since the use of excluded methods in the production of organic foods runs counter to consumer expectations, foods produced with these methods will not be permitted to carry the organic label. (Excluded methods are defined in subpart A and discussed further under Production and Handling (subpart C), Labeling (subpart D), and the National List (subpart G).)

Will genetic engineering be allowed in the production of foods that contain both organic and nonorganic ingredients?

No. For products with mostly organic content—those products where more than half of the ingredients are organic and that have the word, ''organic,'' on the main product label— excluded methods must not be used in the production of any ingredients. Only those products, in which fewer than half of the ingredients are organic and in which the organic ingredients are only identified on the ingredient panel, could contain nonorganic ingredients produced through excluded methods.

We believe consumers have expressed a clear expectation that these methods should not be used in the production of any ingredients contained in mostly organic products. Because prominent use of the word, ''organic,'' on the label of such products reinforces that expectation, we have chosen to prohibit use of excluded methods in production of both the organic and nonorganic ingredients.

We recognize that this policy will place additional burdens on organic food processors and certifying agents because the ability to meet these requirements will depend largely on practices used in conventional agricultural markets. For organic food processors, it may be harder to find sources of nonorganic ingredients that are produced without use of excluded methods. Similarly, certifying agents may face greater difficulty because they will be required to ensure that handlers have complied with this requirement. However, we believe that the need to meet strong consumer expectations outweighs these concerns. Furthermore, we anticipate that as marketplace practices or standards evolve, these practices will be the basis for implementing this provision, providing handlers and certifying agents recognize criteria with which to evaluate sources of nonorganic ingredients in products containing both organic and nonorganic ingredients.

Does this proposal prohibit use of irradiation in organic production?

Yes. This proposal prohibits the use of irradiation in the production of all foods and ingredients that carry the organic label. 275,603 commenters on the first proposal almost universally opposed the use of this technology in organic production systems. Based on this overwhelming public opposition, this proposal prohibits its use in the production of all organic foods even though there is no current scientific evidence that use of irradiation presents unacceptable risks to the environment or human health and may, in fact, offer certain benefits. Because this rule is a marketing standard and consumers have expressed a clear expectation that irradiation should not be used in the production of organic foods, foods produced with this technology will not be permitted to carry the organic label.

The prohibition on irradiation extends to nonorganic ingredients used in mostly organic ingredients—those products where more than half of the ingredients are organic and that have the word, ''organic,'' on the main product label. Only those products, in which fewer than half of the ingredients are organic and in which the organic ingredients are only identified on the ingredient panel, could contain irradiated nonorganic ingredients. We do not believe that this prohibition on irradiation in nonorganic ingredients will place undue burden on either handlers or certifiers because of current labeling requirements for irradiated products.

Does this proposal prohibit use of sewage sludge in organic production?

Yes. This proposal prohibits the use of sewage sludge in the production of all foods and ingredients that carry the organic label. This prohibition extends to nonorganic ingredients used in the production of mostly organic foods—those products in which more than half of the ingredients are organic and that have the word, ''organic,'' on the main product label. Only those products, in which fewer than half of the ingredients are organic and which the organic ingredients are only identified on the ingredient panel, could contain nonorganic ingredients produced using sewage sludge.

275,603 commenters on the first proposal almost universally opposed the use of this technology in organic production systems. Based on this overwhelming public opposition, this proposal prohibits its use in the production of all organic foods, even though there is no current scientific evidence that use of sewage sludge in the production of foods presents unacceptable risks to the environment or human health. We believe consumers have expressed a clear expectation that sewage sludge should not be used in the production of any ingredients contained in mostly organic products. Because prominent use of the word, ''organic,'' on the label of such products reinforces that expectation, we have chosen to prohibit use of sewage sludge in production of both the organic and nonorganic ingredients. We recognize that this policy may place additional burdens on organic food processors and certifying agents. However, we believe that the need to meet strong consumer expectations outweighs these concerns.

Does this proposal set standards for livestock production?

Yes. The proposal sets the first comprehensive standards for production of organic animals and meat products. Under this proposal, use of antibiotics would be prohibited in organic livestock production. The standards also prohibit the routine confinement of animals and require that ruminant animals have access to outdoor land and pasture, although temporary confinement would be allowed under certain, limited circumstances. Animals under organic management must also receive 100-percent organically grown feed. (Organic livestock management issues are discussed in greater detail under subpart C, 205.236 through 205.239.)

Does this proposal prohibit ''ecolabeling''?

No. This proposal only regulates use of the term, ''organic,'' on product labels. Other labels would be allowed as long as they are truthful and not misleading and meet general food labeling requirements. The labeling requirements of this proposal are intended to assure that the term, ''organic,'' and other similar terms or phrases are not used in a way that misleads consumers. Should we find that terms or phrases are being used to represent ''organic'' when the products are not produced to the requirements of this regulation, we would proceed to restrict their use. (Labeling is covered in subpart D.)

Are organic foods pesticide-free?

No. Organic farmers can use natural pesticides to control weeds and insects and maintain the high quality of organic products that consumers have come to expect. Use of synthetic chemical pesticides, however, is prohibited unless specifically allowed on the National List as recommended by the

National Organic Standards Board and approved by the Secretary. (The National List is covered in subpart G, sections 205.600 through 205.607.)

Who needs to be certified?

As a general rule, all organic production and handling operations must be certified. The Act and this proposal, however, do provide for some exceptions. For example, organic operations with less than $5,000 in annual sales of organic products do not require certification. Similarly, organic operations that handle only those products with less than 50 percent organic content or that restrict labeling of organic ingredients to the ingredient information panel do not require certification. Finally, we are not requiring certification of most grocery stores and restaurants (referred to in this proposal as ''retail food establishments'') at this time.

Even where operations do not require certification, however, all organic food products must meet the national standards as described in this proposal. In that way, consumers can be confident that all products labeled as ''organic'' meet the national standards, even if they did not require certification under the NOP. (Certification is covered in subpart E; the exceptions from certification are found in subpart B.)

Will organic farmers have to pay fees?

Organic farmers and other organic operations will have to pay fees for organic certification but will not be charged any fees by USDA. Fees for certification services will be set by the private or State certifying agents. The proposal also requires that certifying agents make their schedule of fees publicly available so that organic operations can plan appropriately and so that they can make informed choices where multiple certifying agents are available. USDA will also review fees charged by certifying agents to ensure that they are reasonable and that they are being applied fairly to all organic operations. Under this proposal, USDA would only charge fees for reviewing (''accrediting'') certifying agents. These fees will primarily be based on the actual costs of the accreditation work done by USDA staff so that certifying agents with smaller and less complex programs will pay lower fees. The proposal also provides for a reduction in the accreditation fees during the first 18 months of the program to provide an incentive for certifying agents to become accredited under the new national program as soon as possible. (Fees are covered in subpart G, §§ 205.640 through 205.642.)

How do I become an accredited certifying agent?

All certifying agents must be accredited by USDA. Certifying agents may apply for accreditation effective with publication of the final rule and are encouraged to apply as soon after publication of the final rule as possible. USDA will provide additional information on applying for accreditation on or about the date of publication of the final rule. This information will be available on the NOP website and by mail upon request.

Applications for accreditation will be handled on a first-come-first-served basis. Those that apply within the first 6 months following publication of the final rule and are determined by the Administrator to meet the requirements for accreditation will be notified of their status in writing on or about 12 months after publication of the final rule. This approach is being taken because of the market advantage that could be realized by accredited certifying agents if USDA did not announce the accreditations simultaneously. (Accreditation is covered in subpart F.)

What are the roles and responsibilities of certifying agents in the National Organic Program?

Certifying agents are the ''front line'' representatives of USDA and play a critical role in the oversight and enforcement of the national organic standards program. Once accredited by USDA, certifying agents are empowered to make key decisions regarding the status of organic operations. Certifying agents review the organic plans of organic operations and are authorized to grant certification to those operations that meet the strict national organic standards. Certifying agents are also responsible for the continuing oversight of organic operations— reviewing annual updates of organic plans, conducting residue analyses, and conducting other monitoring activities.

In cases in which a certifying agent finds that an organic operation does not meet the national standards, the agent is empowered to issue notices of noncompliance and to initiate suspension or revocation of certification. Organic operations can appeal such decisions to USDA but unless the organic operation appeals the certifying agent's decision or can correct the problems identified by the certifying agent, the agent's decision will stand. (Accreditation is covered in subpart F; Compliance is covered in subpart G, §§ 205.660 through 205.668; and Appeals are covered in subpart G, §§ 205.680 through 205.681.]

How will USDA ensure that the National standards are applied fairly and consistently by all certifying agents?

Because this proposal gives certifying agents such an important role in enforcing the national standards, USDA oversight of those certifying agents is particularly important. Under this proposal, all certifying agents, both private and in State organic programs, would have to be accredited by USDA before they could begin to certify organic operations. It is this accreditation process, in which USDA reviews all certifying agents to make sure they understand and can accurately apply the national organic standards, that is USDA's main tool to ensure that the standards are applied fairly and consistently by all certifying agents.

The accreditation process is really one of ongoing oversight by USDA. Accreditation must be renewed every 5 years so that we can be sure certifying agents continue to meet the program standards. USDA will conduct one or more site visits of certifying agents during the period of accreditation as another mechanism of monitoring their compliance. Finally, certified operations may file complaints with USDA if they believe they have been treated unfairly or if a certifying agent is otherwise not following the program requirements. We will investigate these complaints for possible enforcement action.

Can States have organic standards that are more strict than the National standard?

Yes. Some States may have unique environmental or other concerns that they believe require extra conditions above the national standard. In those cases, States would apply to USDA to have their special State program approved by the Secretary.

However, no State would be allowed to set up a program that does not at least meet the national standard. And States would not be allowed to use their programs to keep out or otherwise discriminate against organic products made in another State. (State Programs are covered in subpart G, §§ 205.620 through 205.622.)

What is the timeframe for implementation?

The final rule in this rulemaking process will establish a procedure and a timeframe for implementing the NOP. We expect that the interim period between publication of the final rule in this rulemaking process and the effective date of the program (actual implementation of regulations) will be 18 months. The following is a

preliminary list of several administrative and program issues that must be implemented during that period. Certifying agent applications will be evaluated and accreditation granted. Certifying agents will, in turn, certify production and handling operations to the requirements of these regulations. Equivalency discussions will be held with foreign governments and foreign certifying agents. Guidelines and practice standards on production and handling practices must be finalized and distributed by the NOP. A petition process for recommending amendments to the National List must be developed and distributed. The NOSB will continue to review materials for the National List. State programs may have to make adjustments in their organic certification programs for consistency with the standards of this program. Producers should use the interim period to prepare their production operations to comply with the relevant requirements of this program. Handlers should use the interim period to prepare for necessary changes in the labeling of their products.

Prior Documents in This Proceeding

This proposed rule is issued pursuant to the Organic Food Production Act of 1990 (Act or OFPA), as amended (7 U.S.C. 6501 *et seq.*). This proposal replaces the proposed rule published in the **Federal Register** December 16, 1997. Comments to the first proposal were considered in the preparation of this proposed rule.

The following notices related to the NOSB and the development of this proposed regulation have been published in the **Federal Register**. Five notices of nominations for membership on the NOSB were published between April 1991 and June 1999 (56 FR 15323, 59 FR 43807, 60 FR 40153, 61 FR 33897, 64 FR 33240). Two notices of extension of time for submitting nominations were published on September 22, 1995, and September 23, 1996 (60 FR 49246, 61 FR 49725). Seventeen notices of meetings of the NOSB were published between March 1992 and October 1999 (57 FR 7094, 57 FR 27017, 57 FR 36974, 58 FR 85, 58 FR 105, 58 FR 171, 59 FR 58, 59 FR 26186, 59 FR 49385, 60 FR 51980, 60 FR 15532, 61 FR 43520, 63 FR 7389, 63 FR 64451, 64 FR 3675, 64 FR 28154, 64 FR 54858). One notice of public hearings on organic livestock and livestock products was published on December 30, 1993 (58 FR 69315). One notice specifying a procedure for submitting names of substances for inclusion on the National List was published on March 27, 1995 (60 FR 15744). A rule proposing the NOP was published on December 16, 1997 (62 FR 65850). An extension of the time period for submitting comments to the proposed rule was published on February 9, 1998 (63 FR 6498). One request for comments on Issue Papers was published on October 28, 1998 (63 FR 57624). A notice of a program to assess organic certifying agencies was published on June 9, 1999 (64 FR 30861).

This preamble includes a discussion of the proposed rule and supplementary information, including the Regulatory Impact Assessment, Regulatory Flexibility Act Analysis, Federalism Impact Statement, and Paperwork Reduction Act Analysis. The Civil Rights Impact Analysis is not included as an attachment but may be obtained by writing at the address provided above or via the Internet through the National Organic Program's homepage at: http://www.ams.usda.gov/nop.

National Organic Program Overview

Subpart A—Definitions

Proposal Description

This subpart defines various terms used in this part. These definitions are intended to enhance conformance with the regulatory requirements through a clear understanding of the meaning of key terms.

We have amended terms and definitions carried over from the first proposal where necessary to make their wording consistent with the language used in this proposal. We have removed the definition for the following terms because the terms are not used in this proposal or have been determined to be unnecessary: Active ingredient in any input other than pesticide formulations, active ingredient in pesticide formulations, agroecosystem, botanical pesticides, breeding, chapter, cation balancing agent, certification activities, certification applicant, certified facility, chapter, confirmation of accreditation, contaminant, critical control point, cytotoxic mode of action, degradation, detectable residue level, extract, farm, foliar nutrient, formulated product, fungicide, generic name, incidental additive, inert ingredient in any input other than pesticide formulations, intentionally applied, made with certain organic ingredients, mating disrupter, micronutrient, nonactive residues, nonorganic agricultural ingredient or product, petition, preliminary evaluation, processing methods, production aid, production input, proper manuring, putrefaction, site evaluation, soil amendment, split operation, subtherapeutic, suspension of accreditation, synergist, synthetic volatile solvent, treated, untreated seeds, USDA seal, and weed. We received comments on some of the definitions that have been deleted. We have not addressed these comments here because the relevant definitions have been deleted.

Definitions—Changes Based On Comments

This subpart differs from our first proposal in several respects as follows:

(1) We have amended the term, ''audit trail,'' by replacing the category, ''organic'' or ''made with certain organic ingredients,'' with ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients),'' or agricultural product containing less than 50 percent organic ingredients identified as organic in an ingredients statement. We have taken this action to clarify the definition as requested by several commenters.

(2) We have amended the term, ''buffer area,'' to ''buffer zone'' and amended the term by replacing ''a certified farm or portion of a farm'' with ''a certified production operation or portion of a production operation.'' A few commenters suggested including a minimum size for the buffer zone and specifying that buffer zones must be uncropped vegetated areas. The appropriate size and type of a buffer zone is highly site-specific and cannot be rigidly specified for all locations without placing unreasonable burdens on some producers. Several commenters supported determination of the appropriate buffer zone size and type by the producer in consultation with the certifying agent. Additional information on this issue can be found at subpart C, Crop Production, Changes Requested But Not Made, item 1.

(3) We have amended the definition of the term, ''certification or certified,'' to make the language in the definition consistent with the language of this proposal. We have also removed the language concerning the information to be found on a certificate. Commenters suggested amending the definition by adding the words, ''annual'' and ''based on an on-site inspection and comprehensive review of the operation.'' Other commenters recommended deleting the reference to products on a certificate because it is the operation, not the product, that is certified. We have not made the suggested additions because the issues are adequately addressed in the regulations. We have removed the language concerning information found on a certificate because this information

is adequately addressed in the regulations.

(4) We have amended the definition of ''certifying agent'' to clarify that the term only applies to State-entity and private-entity certifying agents. We have taken this action because there was some confusion among commenters over whether the original definition included a State program's governing State official.

(5) We have amended the definition of ''commercially available'' by removing the phrase, ''to be feasibly and economically used.'' We have taken this action because we agree with commenters that use of the phrase provides an opportunity for producers and handlers to avoid use of preferred inputs. We have also clarified that ''commercially available'' applies to processors by including the words, ''or processing ingredient.'' Additional information on this issue can be found at subpart C, Production and Handling (General), Changes Requested But Not Made, item 2.

(6) We have amended the definition of ''compost'' by referring to compost as ''the product of a carefully managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil.'' We also state that ''composting'' must use methods to raise the temperature of raw materials to the levels needed to stabilize nutrients and kill pathogens. Specific instructions on the production of compost for use in organic production has been referenced to the National Resources Conservation Service's (NRCS) practice standard for a composting facility (Code 317). The NRCS practice Standard provides a field tested and verifiable procedure for producing compost. We have made these changes because commenters suggested that we clarify the meaning of compost. Several commenters stated that the definition should include rules about what kinds of materials are acceptable for use in compost. Additional information on this issue can be found at subpart C, Production and Handling (General), Changes Based On Comments, item 4.

(7) We have amended the definition of ''crop rotation'' by adding a statement about the relationship of crop rotation to perennial crops as suggested by an industry association.

Several commenters suggested inserting references to the use of legumes and sod as essential to crop rotation. The benefits achieved through the use of legumes and sod could be fulfilled through many types of rotation plans, which could only be developed according to the site-specific climate, soil type, and type of crops or livestock produced on a given operation. In the interest of flexibility this proposal does not specify what specific crops have to be included in a crop rotation. The issue addressed in this suggestion is addressed in the crop rotation practice standard at § 205.205. Additional information on crop rotation can be found at subpart C, Production, Changes Based On Comments, item 5.

(8) We have amended the definition of ''disease vectors'' by adding that disease vectors include plants and animals that transmit disease organisms or pathogens which may attack crops or livestock. A few commenters pointed out that the definition as originally proposed was technically inaccurate because it did not address the transmission of disease organisms to crops or livestock.

(9) We have rewritten the definition of ''employee'' to provide that an employee is any person providing paid or volunteer services for a certifying agent. A few States requested that the definition clearly reference volunteers. A trade association recommended expanding the definition to include any person who works for a certifying agent. We have included volunteers in this proposal because of their substantial use by some certifying agents. Other States suggest changing ''certification decisions'' to ''certification activities'' to include any person who is involved in the certification process. We have addressed the commenters' concern by referring to services provided by the employee for the certifying agent. A few States stated that the definition needs to clarify who is the employer of an independent inspector. An independent inspector would not be included in the definition of employee. Such persons are considered to be contractors. Some States expressed concern regarding the use of volunteers from certified production and handling operations. Section 205.501(a)(11) requires that a certifying agent prevent conflicts of interest by not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected, except that a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption may accept voluntary labor from certified operations. Under this exception all volunteers would be excluded from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the prior 12-month period. Additional information on conflicts of interest can be found at subpart F, Changes Based On Comments, items 4 and 5, and subpart F, Changes Requested But Not Made, items 5, 6, 7, and 8; subpart F, Additional Provisions, item 2.

(10) We have rewritten the definition of ''fertilizer'' to provide for the inclusion of minor nutrients and trace elements with the three primary nutrients (nitrogen, phosphorus, potassium) contained in a substance or a blended substance utilized in a soil fertility program. This is a generic definition of fertilizer. Issues concerning what substances may be present in a fertilizer for organic production are addressed in subpart C of this proposal.

(11) We have amended the definition of ''handle'' by providing that the term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler. This change was made because we found merit in a certifying agent's concern that farmers were turned into handlers by definition. This was not our intent.

(12) We have amended the definition of ''inspector'' to make terms used in the definition consistent with terms used in this proposal and to remove the phrase, ''who is qualified.'' A State certifying agent suggested deleting the phrase, ''who is qualified,'' because the issue of inspector qualification is more appropriately addressed in the regulations. We concur that the definition of ''inspector'' does not need to address the issue of qualifications, especially in light of the fact that certifying agents are required by these regulations to use qualified inspectors.

(13) We have amended the definition of ''livestock'' by adding reference to the production of fiber, feed, and other agricultural-based consumer products and by providing that ''livestock'' shall not include fish or bees for the production of food, fiber, feed, or other agricultural-based consumer products. A trade association and several States recommended adding fibers to the definition. We have added fiber, feed, and other agricultural-based consumer products to the definition to capture all types of consumer products that would be produced from livestock. We have excluded aquatic animals from the definition of livestock pending future development of detailed practice standards for specific aquatic animals. We have also excluded bees from the definition of livestock pending future National Organic Standards Board (NOSB or Board) review and recommendations on apiculture.

Additional information on this issue can be found at subpart C, Livestock Production, Changes Based On Comments, items 3 and 4.

(14) We have amended the definition of ''market information.'' A commenter suggested that the definitions of the terms, ''labeling'' and ''market information,'' were difficult to distinguish from one another and needed clarification. We have added language to make a distinction between the two terms. ''Market information'' now includes the phrase, ''distributed, broadcasted, or made available outside of retail outlets.'' This phrase indicates that any information distributed, broadcasted, or made available outside of retail outlets to assist in the sale or promotion of a product falls under the ''market information'' category. ''Labeling'' includes any information displayed or made available in retail outlets on or about the product.

(15) We have amended the definition of ''organic'' to clarify that the term, ''organic,'' is used as a labeling term. Commenters, including several States, stated that the definition repeated the proposed requirements for allowing the use of ''organic'' on a product label. They suggested amending the definition to clarify that the term, ''organic,'' is used as a labeling term. We made the suggested change because we agree that the definition unnecessarily repeated regulatory information and that use of the term, ''organic,'' is intended as a labeling term.

(16) We have amended the definition of ''producer'' to clarify that the term includes the production of fiber and other agricultural-based consumer products. Several States suggested that the definition of ''producer'' be amended to clarify that a producer could also be growing or producing a fiber product. We agree that this clarification is needed and have also added reference to ''other agricultural-based consumer products'' to further clarify that the term includes all agricultural-based consumer products produced by a producer.

(17) We have changed the definition of ''routine use of parasiticide'' to the definition recommended by the NOSB. Commenters suggested removing ''without cause'' from the definition in the first proposal and adding such phrases as ''without an indication of illness from parasites,'' ''administration with need based on the presence of a diagnosed problem with parasites,'' and ''with or without cause.'' The NOSB's definition solves the problems caused by the use of the phrase, ''without cause.'' Additional information on this issue can be found at subpart C, Livestock Production, Changes Based On Comments, item 9.

(18) We have amended the definition of ''slaughter stock'' by changing ''human consumption'' to ''consumption by humans and other animals.'' A few commenters recommended deleting the word, ''human,'' to indicate that organic livestock may also be used to produce pet food. We agree that slaughter stock may be used in the production of products for consumption by humans and other animals.

(19) We have amended the term, ''soil quality,'' and its definition by referencing ''water'' in the term and the definition. This change was made because of the reference to ''soil and water quality'' in § 205.200 of this proposal. Several State commenters stated that the definition of ''soil quality'' was too vague and would pose problems in enforcing a requirement that addressed the effect of various practices on soil quality. Other commenters requested expansion of the definition to include a discussion of why soil quality is important and what functions healthy soil serves in an organic production system. Another State suggested expanding the definition to include water quality, since there were several references in the regulations to effects on soil or water quality. The importance of soil quality has been addressed under subpart C of this proposal. We acknowledge that the phrase, ''soil and water quality,'' is used in subpart C and have, therefore, expanded the term, ''soil quality,'' to ''soil and water quality'' and amended the definition accordingly. We have also added a new phrase to the previous definition to acknowledge that one important criterion of soil and water quality is the control of environmental contaminants. The determination of which observable indicators to monitor and how to interpret the observations will be subject to documentation in the organic system plan and consultation between the producer and the certifying agent. Guidance will be provided to certifying agents through program manuals. Additional information on this issue can be found at subpart C, Production and Handling (General), Changes Based On Comments, item 2.

(20) We have amended the term, ''governing State official,'' to ''State program's governing State official'' and retained the definition to clarify the difference between a State certifying agent and a governing State official. We have used the term, ''State program's governing State official,'' throughout this proposal. A trade association and a State recommended removing the word, ''certification,'' from the definition. We have not made this change because the term is meant to identify the person responsible for administering the State's organic certification program. By ''State organic certification program,'' we mean the law, regulations, and any policies and procedures established by the State to govern the organic certification of producers or handlers by State or private certifying agents.

(21) We have amended the definition of ''unavoidable residual environmental contamination.'' Commenters stated that USDA should set levels rather than make case-by-case decisions regarding residual environmental contamination. They suggested that background levels could be used to determine whether land exceeds the level. Another commenter requested a clear statement of ''unavoidable'' and ''contamination'' to facilitate enforcement. Some States stated that there should be a level that is unacceptable for organic agriculture. A commenter suggested that the definition read, ''The presence of a material prohibited in organic production, processing, or handling in soil, crop, or food that occurs as a result of factors beyond the control of the producer, processor, or handler.'' Another commenter suggested that the definition read, ''Background levels of prohibited substances at a site which are clearly beyond the control of a certified organic farm operator through notices to neighbors, careful avoidance of abnormally precontaminated sites, and establishment of buffer zones.'' In this proposal, we have defined ''unavoidable residual environmental contamination'' as ''background levels of naturally occurring or synthetic chemicals that are persistent in the soil or present in organically produced agricultural products that are below established tolerances.''

Definitions—Changes Requested But Not Made

This subpart retains from our first proposal terms and their definitions on which we received comments as follows:

(1) A few commenters requested that the definition of ''Administrator'' be revised to provide that authority to administer the National Organic Program may be delegated to a State official. We have not made the recommended change because the definition of ''Administrator'' merely addresses the top official of the Agricultural Marketing Service (AMS) and any AMS official to whom the Administrator may delegate authority. The definition is not meant to address working relationships established

between AMS and a State or State entity.

(2) An environmental group requested that we delete the phrase, ''other than during the manufacture of a multiingredient product containing both types of ingredients,'' from the definition of ''commingling.'' This proposal requires that a handler prevent the commingling of organic and nonorganic products but permits use of the word, ''organic,'' in labeling a product made with organic and nonorganic ingredients in accordance with these regulations. Therefore, it is necessary to indicate that the term, ''commingling,'' does not apply to the manufacture of multiingredient products produced in accordance with these regulations.

(3) A farmers' association recommended that the Secretary delegate authority for determining crop year to certifying agents because crop year will vary from region to region. We have found no compelling reason to make certifying agents responsible for determining crop year and have not made the recommended change.

(4) A few commenters requested that the definition of ''handling operation'' be amended to exclude retailers of prepackaged agricultural products. This change is unnecessary because such retailers are excluded by the definition of ''handling operation'' through the phrase, ''except final retailers of agricultural products that do not process agricultural products.''

(5) Several commenters, including a State department of agriculture, recommended elimination of the exception for weight labels in the definition of ''label.'' We have not made the recommended change to the definition of ''label'' because, as used in this proposal, ''label'' is intended to represent the organic nature of the product. A weight label that does not refer to the organic nature of the product would not constitute a label for the purposes of this proposal.

(6) A commenter requested that the definitions for ''labeling'' and ''market information'' be amended to refer only to products produced by the seller. We have not made this requested change because changing the definitions to only include products produced by the seller would severely restrict the application of the terms, ''labeling'' and ''market information.'' As defined, ''labeling'' and ''market information'' correctly include any information that may be presented to consumers concerning all products sold whether produced by the seller, most likely a retail outlet, or produced by a production or handling operation from which the seller acquired the products.

(7) A commenter requested that we include definitions for ''manure'' and ''aged or rotted manure.'' Under this proposal it is not necessary to define either term.

(8) An environmental organization requested that a phrase be added to the definition of ''mulch'' to indicate that acceptable mulch materials leave no chemical or toxic residues. This proposal allows the use of composted plant and animal wastes obtained from nonorganic sources, such as commercial compost products. Uncomposted plant or animal waste material which has been treated with a substance can be as utilized as a mulch provided the substance appears on the National List or complies with the OFPA. Off-farm plant and animal wastes from food processing, municipal yard waste facilities, and other sources are used extensively in existing organic operations and generally permitted by organic certification programs. Using such organic wastes is consistent with a system of organic production and handling, which calls for recycling organic wastes to return nutrients to the land. We believe that concerns about potential contaminants in plant and animal waste materials can be addressed by the requirement in this proposal that these materials be managed in a manner that prevents such contamination. Accordingly, this change has not been made. Additional information on this issue can be found at subpart C, Crop Production, Changes Requested But Not Made, items 2 and 3.

(9) Several commenters suggested adding information to the definition of ''National Organic Standards Board'' to address the role of the NOSB with regard to the National List. This change is unnecessary because the role of the NOSB is adequately covered in section 6517, National List, of the Act.

(10) Numerous comments were received from consumers, environmental groups, and organic producers concerning the definition of the term, ''nonagricultural ingredient.'' Commenters expressed the view that this term represented an attempt by USDA to circumvent the intent of the Act that synthetic ingredients not be permitted in organic processed products. We disagree with the position that the Act prohibits the use of synthetic ingredients in organic processed products. The use of synthetic ingredients in organic processed products is discussed in the preamble to the National List found in subpart G. We have changed the term, ''nonagricultural ingredient,'' to ''nonagricultural substance'' to be consistent with the language used in this proposal. The definition remains the same.

(11) Commenters stated their objection to the use of the term, ''nonsynthetic (natural),'' and its definition. A commenter mistakenly stated that the term, ''natural,'' was defined in the Act. Other commenters felt that use of any term that was not included in the Act was a violation of the Act. Because the term, ''natural,'' is so ambiguous and subject to differing interpretations, the term, ''nonsynthetic,'' as used throughout this regulation, represents an important clarification of the intent of the Act, and we have, therefore, retained it in this proposal.

(12) A few commenters requested that the definition of ''petition'' be amended by adding the phrase, ''to the National Organic Standards Board,'' immediately following the word, ''submitted.'' We have not made the requested change for two reasons. First, the change is unnecessary. Second, petitions, whether addressed to the NOSB or National Organic Program (NOP) Staff, will be received by the NOP because the administrative functions of the NOSB are performed at the NOP office. Petitions received will be distributed by the NOP to the NOSB and appropriate technical reviewers.

(13) A producers association stated that the definition for ''processing'' was confusing with regard to the difference between a handler and a processor. A handling operation that performs any of the activities listed in the definition of processing becomes a processor. We have found no compelling reason to revise this comprehensive definition for processing, which comes directly from the Act. A commenter suggested that this definition be changed to include repackaging for weight. In addition to the definition being stipulated by the Act, affixing a weight label to a product is a normal retail activity that does not warrant the expense and effort necessary to certify all retailers who routinely affix weight labels to organic product.

(14) A few commenters requested that the definition of ''State organic certification program'' be amended by adding a statement indicating that a State program could have additional requirements. This issue is addressed in subpart G, State Organic Certification Programs, Proposal Description.

(15) A technical institute recommended including genetically engineered organisms and their products in the definition of ''synthetic,'' and an environmental

group wanted the definition to include the combustion of minerals. We have not amended the definition as given in the Act because it already includes the combustion of minerals, which are chemically changed by the process of combustion. We also do not consider it necessary to classify genetically engineered organisms as either synthetic or nonsynthetic for the purposes of this regulation, since these organisms and their products are prohibited for use in organic production or handling regardless of whether or not they are synthetic.

(16) A commenter recommended adding the word, ''synthetic,'' immediately preceding the word, ''substances,'' in the second sentence of the definition of ''system of organic farming and handling.'' We disagree with this suggestion because ''substances'' as used in this definition could be synthetic or nonsynthetic. A few commenters requested deletion of the word, ''extraneous,'' as a modifier of ''synthetic additives'' in the definition of ''system of organic farming and handling.'' The commenters stated that use of the word, ''extraneous,'' implied that synthetic additives can be used in organic processed products. Synthetics may be used in processed products if the substance is included on the National List. Additionally, the word, ''extraneous,'' modifies the word, ''processing,'' in the definition, and we consider use of extraneous processing to be inconsistent with organic handling. For these reasons, we have not removed the word, ''extraneous,'' from the definition. We have, however, amended the term, ''system of organic farming and handling,'' by deleting ''farming'' and inserting ''production.'' The definition for the term, ''system of organic production and handling,'' is unchanged. We have taken this action to make the term consistent with the language of this proposal. Additional information on this issue can be found at subpart C, Production and Handling (General), Changes Requested But Not Made, item 1.

(17) Several commenters, including a State Department of Agriculture and a fishery association, requested that wild game and aquatic animals be included in the definition of ''wild crop.'' Regarding aquatic animals, we intend to develop detailed practice standards for specific aquatic species, which will be published for comment and finalized prior to the implementation of the NOP. Given the virtual absence of recognized certification programs for aquatic operations, including aquaculture, there are no U.S. models on which to base national standards. Additional information on this issue can be found at subpart B, Changes Requested But Not Made, item 11 and subpart C, Crop Production, Changes Requested But Not Made, item 7. Accordingly, we have not made the requested changes to the definition of ''wild crop.''

Definitions—Additional Provisions

Upon further review of the definitions in the first proposal, we have decided to propose the following additions and changes.

Amended Definitions

(1) We have amended the definition of ''accreditation'' to include foreign entities as now provided for in subpart F, Accreditation. Additional information on including foreign entities in accreditation can be found at subpart B, Additional Provisions, item 1, and subpart F, Changes Based On Comments, item 1.

(2) We have amended the definition of ''allowed synthetic'' by replacing ''for use in organic farming'' with ''for use in organic production, or handling.'' This correction was necessary because the National List includes synthetic substances used in organic production and handling.

(3) We have amended the terms, ''certified organic farm,'' ''certified organic handling operation,'' and ''certified organic wild-crop harvesting operation,'' with the term, ''certified operation.'' The term, ''certified operation,'' is used throughout this proposal to refer to a crop or livestock production, wild-crop harvesting, or handling operation or portion of an operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and regulations in this part. We have taken this action to simplify the regulatory language.

(4) We have amended the term, ''cultural,'' to ''cultural methods'' and amended the definition by removing all references to livestock. We have taken this action because this proposal does not refer to cultural methods with reference to livestock health care.

(5) We have amended the definition of ''field'' by replacing ''farm'' with ''production operation.'' This action was taken because ''farm'' has been replaced by ''production operation'' throughout this proposal.

(6) We have amended the definition of ''handler'' by adding the phrase, ''including producers who handle crops or livestock of their own production.'' We have made this change to clarify that producers who handle their own production become handlers under the regulations. Such producer/handlers must be certified as a handler.

(7) We have amended the term, ''inert ingredient in pesticide formulations,'' to ''inert ingredient.'' We have also amended the definition by specifying that the pesticide product is used in organic crop or livestock production and handling. These changes have been made to make the term and its definition consistent with the language used in the National List. This proposal takes a different position on inert ingredients, as explained in subpart G, National List, Changes Based on Comments, item 6, than was taken in the first proposal. Because of the increased importance of inert ingredients in this proposal, we have rejected the position of the few commenters who recommended removal of this definition.

(8) We have amended the term, ''organic plan,'' to ''organic system plan'' and made editorial changes to the definition to make the term and language of the definition consistent with the language in this proposal.

(9) We have amended the definition of ''peer review panel'' by removing ''to assist in evaluating the performance of a certifying agent'' and inserting ''to assist in evaluating applicants for accreditation as certifying agents.'' This change clarifies that the role of the peer review panel is to evaluate applicants for accreditation. Additional information on ''peer review panel'' can be found at subpart C, Proposal Description, Production and Handling (General).

(10) We have amended the definition of ''person'' by adding ''contractor'' to clarify that, when the regulations use ''person,'' the meaning includes ''contractors.''

(11) We have amended the definition of ''records'' by removing the record examples. A trade association and several States recommend adding ''process flow charts'' to the examples of records. Another commenter, who does not want to give USDA unlimited access to personnel files, suggested the creation of a specific list of records to be maintained. We have rewritten the recordkeeping provisions, removing all references to specific records or types of records which must be maintained. We have taken this action because we believe that it is impracticable to specify in detail every class of records which may be found essential in demonstrating compliance with the Act and regulations. Different types of certified production and handling operations will, by the very nature of their business, be required to maintain different records to establish their

compliance with the Act and regulations. Additional information on the issue of listing every class of records which may be found essential in demonstrating compliance with the Act and regulations can be found at subpart B, Changes Based On Comments, item 6.

(12) We have amended the definition of ''State.'' Addition of the term, ''State entity,'' necessitated our amendment of the definition of ''State'' to clarify that State means the States of the United States of America.

(13) We have amended the term, ''system of organic farming and handling,'' to ''system of organic production and handling'' and retained the original definition in this proposal. The original definition was crafted to be consistent with the requirements of the Act. We have changed ''farming'' to ''production'' to provide a more encompassing term, which may come to include such diverse activities as hydroponics, green house production, and harvesting of aquatic animals. The purpose of the original definition was to describe practices and substances consistent with systems of organic farming and organic handling as required by the Act and to provide an explicit reference point for determining which practices and substances are most consistent with these systems. Several commenters suggested that the definition include the concepts, ''agroecosystem health,'' ''ecological harmony,'' and ''biological diversity.'' Commenters also suggested including definitions for ''organic agriculture,'' ''organic farming,'' and ''transition to organic.'' This definition is intended to clarify regulatory provisions in this proposal and is not intended as a broad philosophical statement. The terms, ''organic agriculture,'' ''organic farming,'' and ''transition to organic,'' are not used in this proposal and, therefore, are not defined.

(14) We amended the definition of transplant to prevent confusion with a related term, ''seedling.'' While the terms, ''transplant'' and ''seedling'' are often used interchangeably, the Act treats them as distinct and establishes separate regulatory requirements. We have determined that the physical process of moving and replanting a seedling results in that seedling becoming a transplant. We have created this distinction to be able to enforce the full requirements of the Act. Additional information on ''transplant'' can be found at subpart C, Crop Production, Changes Based On Comments, item 4.

New Definitions

(1) We have defined ''accredited laboratory.'' Information concerning ''accredited laboratory'' can be found at subpart G, Inspection and Testing, Reporting, and Exclusion from Sale, Proposal Description.

(2) We have defined ''action level.'' Information concerning ''action level'' can be found at subpart G, Inspection and Testing, Reporting, and Exclusion from Sale, Changes Based On Comments, item 2.

(3) We have defined ''agricultural inputs.'' Information concerning ''agricultural inputs'' can be found at subpart G, Inspection and Testing, Reporting, and Exclusion from Sale, Changes Based On Comments, item 1.

(4) We have defined ''Agricultural Marketing Service (AMS) '' because the term is used throughout this proposal.

(5) We have defined ''breeder stock.'' We have added this definition because this proposal establishes conditions for the administration of an allowed synthetic parasiticide to livestock producing offspring for incorporation into an organic operation. We have also proposed conditions under which dairy stock, whose milk or milk products are to be sold, labeled, or represented as organically produced, may be treated with allowed synthetic parasiticides. Additional information on this issue can be found at subpart C, Livestock Production, Changes Based On Comments, item 9.

(6) We have defined ''bulk.'' Information concerning ''bulk'' can be found at subpart D, Additional Provisions, item 7.

(7) We have defined ''claims.'' Information concerning ''claims'' can be found at subpart D, Changes Based On Comments, item 1.

(8) We have defined ''detectable residue.'' Information concerning ''detectable residue'' can be found at subpart G, Inspection and Testing, Reporting, and Exclusion from Sale, Proposal Description and at Changes Based On Comments, item 2.

(9) We have defined ''drift.'' Information concerning ''drift'' can be found in subpart G, Residue Testing, changes based on comments, item 2.

(10) We have defined ''estimated national mean.'' Information concerning ''estimated national mean'' can be found at subpart G, Inspection and Testing, Reporting, and Exclusion from Sale, Proposal Description and at Changes Based On Comments, item 2.

(11) We have defined ''excluded methods.'' As a result of extensive public comment, we have revised the definition of certain methods to be excluded from organic production systems. Many commenters suggested that we use the definition for certain methods to be excluded from organic production systems proposed by the NOSB. This proposal essentially adopts that definition. ''Excluded methods'' refers to a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods would include recombinant DNA, cell fusion, and micro-and macroencapsulation. Such methods would not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

We recognize that the phrases, ''natural conditions or processes'' and ''not considered compatible with organic production,'' may be subject to interpretation. We have proposed to use these phrases for two reasons. First, ''natural conditions or processes'' is used in the NOSB and American Organic Standards definitions, both of which were the result of consultation with organic industry and consumer stakeholders and, thus, accurately reflect current industry practices as well as consumer preferences. Second, we recognize that industry and consumer expectations regarding the products of these techniques in organic production systems may evolve. We believe that, taken together, these phrases allow for a degree of flexibility to ensure that our regulations continue to accurately reflect industry practices and consumer preferences. In cases where questions may arise regarding a specific technique, we anticipate that such questions would be resolved by the Administrator based on recommendations from the NOSB.

(12) We have defined ''feed additive.'' Information concerning ''feed additive'' can be found at subpart C, Livestock Production, Changes Based On Comments, item 7.

(13) We have defined ''feed supplement'' Information concerning feed supplement'' can be found at subpart C, Livestock Production, Changes Based On Comments, item 7.

(14) We have defined ''forage.'' Information concerning ''forage'' can be found at subpart C, Livestock Production, Changes Based On Comments, item 4.

(15) We have defined ''immediate family.'' Information concerning ''immediate family'' can be found at subpart F, Changes Based On Comments, items 14 and 15; Changes Requested But Not Made, item 18; and Additional Provisions, item 2.

(16) We have defined ''ingredient'' because the term is used throughout subpart D.

(17) We have defined ''inspection'' because the term is used throughout subparts E and F.

(18) We have defined ''lot.'' Information concerning ''lot'' can be found at subpart D, Proposal Description and at Additional Provisions, item 6.

(19) We have defined ''natural resources of the operation.'' This definition has been added to provide greater context for evaluating the ''maintain or improve'' requirement for a system of organic production and handling. Information concerning ''natural resources of the operation'' can be found at subpart C, Production and Handling (General), Changes Based On Comments, item 2.

(20) We have defined ''nonretail container.'' Information concerning ''nonretail container'' can be found at subpart D, Proposal Description and at Additional Provisions, item 6.

(21) We have defined ''practice standard.'' Practice standards have been added to this proposal in response to commenter requests for more specific guidelines for measuring the performance of an organic system of production and handling. A practice standard is a series of specific guidelines, requirements, and operating procedures through which a production or handling operation implements a required component of its organic system plan. For example, this proposal contains a practice standard for soil fertility and crop nutrient management which describes the tillage practices, sources and handling restrictions for nutrients, and prohibited activities that a production operation must comply with. There are specific practice standards applicable to crop, livestock, and wild-crop production, and handling operations. We are also proposing to incorporate the terms of the NRCS practice standard for a composting facility into the requirements of this proposal. Additional information on ''practice standards'' can be found at subpart C, Production and Handling (General), Changes Based On Comments, item 4.

(22) We have defined ''private entity'' because the term is used throughout subpart F to differentiate between governmental (State entity) and nongovernmental (private entity) organizations providing certification services.

(23) We have defined ''production lot number.'' Information concerning ''production lot number'' can be found at subpart D, Proposal Description and at Additional Provisions, item 6.

(24) We have defined ''residue testing'' because the term is used throughout the inspection and Testing, Reporting, and Exclusion from Sale portion of subpart G.

(25) We have defined ''retail food establishment.'' Information on ''retail food establishment'' can be found in subpart B, Applicability, Proposal Description and Additional Provisions, item 2.

(26) We have defined ''sewage sludge.'' This term has been added and defined as synonymous with ''biosolids'' to incorporate the Environmental Protection Agency's regulatory language for this category of materials. Information concerning ''sewage sludge'' can be found at subpart C, Crop Production, Changes Based On Comments, item 1.

(27) We have defined ''State entity.'' This proposal provides for the accreditation of domestic, tribal government, and foreign governmental subdivisions that provide certification services. We refer to such an entity in this proposal as a ''State entity.'' Additional information on ''State entity'' can be found at subpart F, Changes Based On Comments, item 1.

(28) We have defined ''tolerance.'' Information concerning ''tolerance'' can be found at subpart G, Inspection and Testing, Reporting, and Exclusion from Sale, Proposal Description and at Changes Based On Comments, item 2.

Subpart B—Applicability

This subpart provides an overview of what has to be certified under the National Organic Program (NOP), describes exemptions and exclusions from certification, addresses use of the term, ''organic,'' and addresses recordkeeping by certified production and handling operations.

Proposal Description

Except for exempt and excluded operations, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients)'' must be certified. Certified operations must meet all applicable requirements of these regulations.

Certifying agents will begin the process of certifying organic production and handling operations to the national standards upon receipt of their accreditation from the Administrator. All production and handling operations certified by an accredited certifying agent will be considered certified to the national standards until the certified operation's anniversary date of certification. We are providing this phase-in procedure for production and handling operations certified by newly accredited certifying agents because we believe that such certifying agents will, upon publication of the final rule, demonstrate their eligibility for accreditation by applying the national standards to the certification and renewal of certification of their clients. We are also providing this phase-in procedure to provide relief to certified operations which would otherwise have to be certified twice within a 12-month period (prior to their certifying agent's accreditation and again following their certifying agent's accreditation). This relief will only be available to those certified operations certified by a certifying agent that receives its accreditation within 18 months from the date of publication of the final rule. We anticipate that certifying agents and production and handling operations will move as quickly as possible to begin operating under the national organic standards. We are providing this substantial phase-in period because accredited certifying agents will have to schedule on-site inspections around varying growing seasons and because certifying agents and production and handling operations will need time to adapt to the new national organic standards.

Exempt and Excluded Operations. This regulation establishes several categories of exempt or excluded operations. Exempt operations derive their exemption from the Act while excluded operations are excluded as a result of a Departmental policy decision. An exempt or excluded operation does not need to be certified. However, operations that qualify as exempt or excluded operations may elect to apply for certification. A production or handling operation that is exempt or excluded from obtaining certification still must meet other regulatory requirements contained in this rule as explained below.

Exempt Operations. (1) A production or handling operation that has $5,000 or less in gross agricultural income from organic sales annually is exempt from certification and does not need to submit an the organic system plan to anyone for acceptance or approval. However, an exempt producer or handler must comply with the labeling requirements of § 205.309 and the organic production and handling requirements applicable to its type of operation. For example a producer of organic vegetables, that performs no handling functions, would have to comply with the labeling requirements

of § 205.309 and the applicable production requirements in §§ 205.202 through 205.207. The labeling and production and handling requirements protect the integrity of organically produced products.

(2) A retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from all of the requirements in these regulations.

(3) A handling operation or portion of a handling operation that handles agricultural products containing less than 50 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in these regulations, except the recordkeeping provisions of § 205.101(c); the provisions for prevention of contact of organic products with prohibited substances in § 205.272; and the labeling regulations in § 205.309. The recordkeeping provisions maintain an audit trail for organic products. The prevention of contact with prohibited substances and the labeling requirements protect the integrity of organically produced products.

(4) If a handling operation or portion of a handling operation that handles agricultural products containing at least 50 percent organic ingredients by weight (excluding water and salt) does not use the word, ''organic,'' on any package panel other than the information panel, it is exempt from the requirements in these regulations, except the recordkeeping provisions of § 205.101(c); the provisions for prevention of contact of organic products with prohibited substances as provided in § 205.272; and the labeling regulations in § 205.309. The recordkeeping provisions maintain an audit trail for organic products. The prevention of contact with prohibited substances and labeling requirements protect the integrity of organically produced products.

As noted above, exempt handling operations producing multiingredient products must maintain records as required by § 205.101(c). This would include records sufficient to: (1) prove that ingredients identified as organic were organically produced and handled, and (2) verify quantities produced from such ingredients. Such records must be maintained for no less than 3 years and the operation must allow representatives of the Secretary and the applicable State program's governing State official access to the records during normal business hours for inspection and copying to determine compliance with the applicable regulations.

Excluded Operations. (1) A handling operation or portion of a handling operation that sells organic agricultural products labeled as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients)'' that are packaged or otherwise enclosed in a container prior to being received or acquired by the operation, remain in the same package or container, and are not otherwise processed while in the control of the handling operation is excluded from the requirements in these regulations, except for the provisions for prevention of commingling and contact of organic products with prohibited substances in § 205.272. The requirements for the prevention of commingling and contact with prohibited substances protect the integrity of organically produced products.

This exclusion will avoid creating an unnecessary barrier for handlers who distribute nonorganic products and who want to offer a selection of organic products.

(2) A retail food establishment or portion of a retail food establishment that processes or prepares, on the premises of the retail food establishment, raw and ready-to-eat food from certified agricultural products labeled as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients)'' is excluded from the requirements in these regulations, except for the provisions for prevention of contact of organic products with prohibited substances as provided in § 205.272; and the labeling regulations in § 205.309. The prevention of commingling and contact with prohibited substances and labeling requirements protect the integrity of organically produced products.

Excluded retail food establishments include restaurants; delicatessens; bakeries; grocery stores; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat food.

We have excluded such retail food establishments because comments to the first proposal concerning the issue of certification of retail food establishments were completely divergent. Comments ranged from the certification of all retail food establishments to exclusion of all retail food establishments. There is clearly a great deal of public concern regarding the handling of organic products by retail food establishments. Someday retail food establishments may be subject to regulation under this NOP. Any such regulation would be preceded by rulemaking with an opportunity for public comment. Our exclusion of retail food establishments from this proposal does not prevent a State from developing an organic retail food establishment certification program or otherwise regulating retail food establishments that prepare, package, or process organic agricultural products.

No retailer, regardless of this exclusion and the exceptions found in the definitions for ''handler'' or ''handling operation,'' may sell, label, or provide market information on a product unless such product has been produced and handled in accordance with the Act and these regulations. Any retailer who knowingly sells or labels a product as organic, except in accordance with the Act and these regulations, will be subject to a civil penalty of not more than $10,000 under this program. Such retailer may also be subject to enforcement actions and penalties under Federal statutes and their implementing regulations administered by other agencies of the Federal government.

Recordkeeping Requirements for Certified Operations. A certified operation must maintain records concerning the production and handling of agricultural products that are sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients)'' sufficient to demonstrate compliance with the Act and regulations. Such records must be adapted to the particular business that the certified operation is conducting, fully disclose all activities and transactions of the certified operation in sufficient detail to be readily understood and audited, be maintained for not less than 5 years beyond their creation, and be sufficient to demonstrate compliance with the Act and regulations. Certified operations must make the records required by this regulation available for inspection and copying by authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent. Access to such records must be provided during normal business hours.

Examples of Records. Each exempt, excluded, and certified operation should maintain the records which demonstrate compliance with the Act and the regulations applicable to it and which it believes establish an audit trail sufficient to prove to the Secretary, the applicable State program's governing State official, and the certifying agent that the exempt, excluded, or certified operation is and has been in compliance with the Act and regulations.

Examples of records include: Application and supporting documents for certification; organic system plan and supporting documents; purchased inputs, including seeds, transplants, livestock, and substances (fertilizers, pesticides, and veterinary biologics consistent with the livestock provisions of subpart C), cash purchase receipts, receiving manifests (bills of lading), receiving tickets, and purchase invoices; field records (planting, inputs, cultivation, and harvest); storage records (bin register, cooler log); livestock records, including feed (cash purchase receipts, receiving manifests (bills of lading), receiving tickets, purchase invoices, copies of grower certificates), breeding records (calendar, chart, notebook, veterinary documents), purchased animals documentation (cash purchase receipts, receiving manifests (bills of lading), receiving tickets, purchase invoices, copies of grower certificates), herd health records (calendar, notebook, card file, veterinary records), and input records (cash purchase receipts, written records, labels); producer invoice; producer contract; receiving manifests (bills of lading); transaction certificate; producer certificate; handler certificate; weigh tickets, receipts, and tags; receiving tickets; cash purchase receipts; raw product inventory reports and records; finished product inventory reports and records; daily inventories by lot; records as to reconditioning, shrinkage, and dumping; production reports and records; shipping reports; shipping manifests (bills of lading); paid freight and other bills; car manifests; broker's contracts; broker's statements; warehouse receipts; inspection certificates; residue testing reports; soil and water testing reports; cash receipt journals; general ledgers and supporting documents; sales journals; accounts payable journals; accounts receivable journals; cash disbursement journals; purchase invoices; purchase journals; receiving tickets; producer and handler contracts; cash sales receipts; cash purchase journals; sales invoices, statements, journals, tickets, and receipts; account sales invoices; ledgers; financial statements; bank statements; records of deposit; canceled checks; check stubs; cash receipts; tax returns; accountant's or other work papers; agreements; contracts; purchase orders; confirmations and memorandums of sales; computer data; computer printouts; and compilations of data from the foregoing.

Request for Comment. This proposal provides that all ingredients in a multiingredient product identified as organic must have been produced by a production or handling operation certified by an accredited certifying agent. We are seeking comment on the following question. Should handlers be allowed to identify organically produced products produced by exempt production operations as organic ingredients? Such identification would be restricted to the ingredients list on the information panel. This may provide a wholesale outlet for organically produced agricultural products produced by producers exempted from certification because their gross agricultural income from organic sales totals $5,000 or less annually.

Compliance with Federal Statutes and Regulations. Any agricultural product that is sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients)'' must be produced and handled in accordance with the requirements in these regulations. Organic agricultural products must be produced and handled in compliance with the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, concerning meat, poultry, and egg products; the Federal Food, Drug, and Cosmetic Act; the Federal Insecticide, Fungicide, and Rodenticide Act; and any other applicable Federal statute and its implementing regulations.

Foreign Applicants. The regulations in this part, as applicable, apply equally to domestic and foreign applicants for accreditation, accredited certifying agents, domestic and foreign applicants for certification as organic production or handling operations, and certified production and handling operations unless otherwise specified.

Applicability—Changes Based on Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Exception for Handlers Serving Three or Fewer Certified Operations.* We have removed the provision that would have allowed handlers providing services to fewer than three certified organic producers to operate without separate certification under the NOP (§ 205.201). Such handlers will now have to be certified unless otherwise exempted or excluded from certification under § 205.101 of these regulations. We have taken this action because we believe that the first proposal invites problems, such as making certain that the contracted handler maintains compliance with the Act and regulations, taking enforcement actions against persons violating the Act and regulations, and being equitable to all handlers since large-volume handling operations may qualify for inclusion under the provision on the basis of few clients while small-volume handlers would be disqualified because they have three or more clients.

More than 100 comments were received, most from consumers, in opposition to the provision. Many of the commenters erroneously interpreted the provision as an exemption for handlers of product for less than three certified operations. Most of these commenters expressed the belief that it is a violation of the Act to allow handlers to operate through inclusion under another certified operation's certification rather than through separate certification under the Act and regulations. Several commenters stated that it is unacceptable to exempt handling operations providing services to fewer than three certified entities from separate certification. Several commenters stated that operations that process products from a certified producer should always be certified. Several State departments of agriculture and others stated that the exemption for handlers servicing fewer than three certified operations does not make sense. They emphasized that certified operations could produce very large quantities of organic product and a large-scale handler may contract with only a few certified producer operations. Therefore, they called for elimination of the exemption. A few commenters questioned the certified operation's ability to ensure that the contracted handler maintains compliance with the Act and regulations. They expressed their belief that the certified operation would have no authority to maintain compliance with the Act within a facility it neither owns nor manages.

We never intended to exempt handlers of fewer than three certified operations from certification. Rather, we proposed a means by which handlers of fewer than three certified operations could be covered under the certification of a certified operation for which it provides handling services.

Several of the commenters favored the provision that any handling operation that provides handling services to fewer than three certified entities that produce or handle agricultural products that are or that are intended to be sold, labeled, or represented as organic or made with certain organic ingredients would not be required to be separately certified apart from the operations for which it provides such services. However, supporters of the concept differed in their position on the proposal. Most stated that the provision would work

only if it is made clear that a handler can provide services to only one or two separate entities and qualify for the exemption and only if included in the certifications of and inspected along with the entities for which the handler will provide the services. They further emphasized that all applicable standards must be met. A few supporters recommended that there be a contract between the handler and the certified operation and that the certified operation be responsible for any failure of the handler to adhere to these regulations. Another commenter stated that, if handlers are to be exempt from certification, the qualifying parameter for exemption should be based upon economic value similar to that for production operations.

Two commenters supported the proposal but wanted the fewer-than-three-certified-operations limitation removed. One of the commenters, a nonprofit agricultural organization, expressed the belief that the limitation needlessly restricts commercial activity, invites an excessive amount of paperwork related to certification applications, and provides no greater assurances for quality control. This commenter, referring to the definition of handling operation at section 6502(10) of the Act, interpreted ''to receive or otherwise acquire'' as synonymous with taking legal title to the product. This commenter stated that this interpretation creates a distinct, verifiable threshold which clearly identifies those operations needing to be certified and those that do not need to be certified. Under the commenter's suggested system, handlers who take legal title to organic products assume responsibility for their subsequent handling and are required to have their operations certified. Any handler who works on organic products without taking legal title would have his or her activities approved and monitored by the certifying agent responsible for the product when it arrived at the handler's door. The commenter believes that noncertified handlers who wanted to serve organic customers would quickly learn to provide the quality control and accountability requirements which certifying agents expect to see.

We disagree with the commenters who recommended removal of the fewer-than-three-certified-operations restriction on the grounds that the proposal to limit exemptions to handlers contracting with fewer than three certified operations needlessly restricts commercial activity, invites an excessive amount of paperwork related to certification applications, and provides no greater assurances for quality control. The primary justification given for removal of the fewer-than-three-certified-operations restriction is the belief that any handler who works on organic products without taking legal title would have his or her activities approved and monitored by the certifying agent responsible for the product when it arrived at the handler's door. First, it is unreasonable to expect the certifying agent to be responsible for monitoring noncertified handlers even if they are providing services to an operation certified by the certifying agent. Second, we disagree with the commenter's interpretation that ''to receive or otherwise acquire'' is synonymous with taking legal title to the product. ''To receive or otherwise acquire'' involves the possession, control, or custody of a product. Such possession, control, or custody of a product may or may not involve the transfer of title to the product. In other words, a handler may have possession, control, or custody of the product under a right derived from a certified operation but not under a claim of the handler's title to the product.

(2) *Certification for a Portion of a Production or Handling Operation.* We have clarified that a portion of a production or handling operation can be certified. We have taken this action because we agree with the association commenter who suggested that the Department clarify for potential applicants for certification that a portion of their production or handling operation can be certified. The Act at section 6506(b) authorizes the certification of specific fields of a production operation or parts of a handling operation when: (1) In the case of a production operation or field, the area to be certified has distinct, defined boundaries and buffer zones separating the land being operated through the use of organic methods from land that is not being operated through the use of such methods; (2) the operators of such production or handling operation maintain records of all organic operations separate from records relating to other operations and make such records available at all times for inspection by the Secretary, the certifying agent, and the State program's governing State official; and (3) appropriate physical facilities, machinery, and management practices are established to prevent the possibility of a mixing of organic and nonorganic products or a penetration of prohibited chemicals or other substances on the certified area. This clarification is found at § 205.100 of this proposal.

(3) *Exemption for Operations with $5000 or Less in Income.* We have clarified at § 205.101(a)(1) that the producer and handler exemption from certification applies to production and handling operations that sell agricultural products as organic but whose gross agricultural income from organic sales totals $5,000 or less annually. We have taken this action because of commenter confusion over whether the $5,000 level applied to all sales of agricultural products or just sales of organic agricultural products. This action is consistent with the position of a State department of agriculture, which stated that the $5,000 exemption should apply to organic sales, not sales of all agricultural products. The commenter believes that, as originally proposed, the regulation would limit opportunities for organic industry development, especially for small producers and other small agribusinesses.

(4) *Applicability of Regulation to Exempt Operations.* We have revised the producer and handler exemption, provided to producers and handlers with gross agricultural income from organic sales totaling $5,000 or less annually, to provide that such operations are exempt from certification and do not need to submit an organic system plan to anyone for acceptance or approval but must comply with the requirements for organic production and handling and the labeling requirements for agricultural products produced on an exempt or excluded operation. We have taken this action because the first proposal too narrowly addressed the regulatory requirements that exempt producers must meet. Our purpose is to exempt such production and handling operations from the regulatory and financial burdens of certification but not to exempt them from the standards for organic production and handling. A fundamental concept of this regulation is to establish a label for organic. To the extent that these entities will be using the term, ''organic,'' to describe their product, they must be truthful. If they don't comply with the other requirements of this part, they cannot truthfully describe their product as organic.

Several State commenters expressed the belief that the producer exemption would be too difficult to enforce. Some expressed the belief that exempt production operations would still require monitoring to verify compliance with organic standards. A State department of agriculture commented that some monitoring of uncertified operations would still be needed to verify compliance with standards; otherwise there would be no guarantee that standards would be met for

products being sold as organic. Another State, which expressed strong disagreement with the producer exemption, asked how complaints against such producers would be reconciled if they are exempt from the NOP and do not have to maintain records over a multiple-year period. This commenter stated its intent, under its State program, to require certification of organic production operations producing less than $5,000 in agricultural product yearly. This same commenter acknowledged the Federal program's obligation to provide the exemption as required by section 6505(d) of the Act.

A producer raised the issue of having exempt operations provide affidavits of compliance with the Act and regulations except for certification. A certifying agent made the observation that the rule as first proposed would not permit exempt producers, whether operating under an affidavit or not, to sell any of their products to a certified operation for further processing unless they were fully certified. This certifying agent stated that it did not believe excluding exempt producers from selling any of their products to a certified operation for further processing unless they were fully certified was consistent with the intent of the Act.

We disagree with both commenters. First, we believe that an affidavit program for exempt producers, opting to exercise their right to the exemption, would impose unnecessary regulation upon entities that the Act clearly intended not to impose such regulation upon. Second, an affidavit program would create a regulatory burden on the Department and certifying agents that would not be justified by the size of such operations. We recognize, as pointed out by commenters, that some State programs currently require organic production operations that would be exempt under this national program to register with the State and to comply with requirements such as filing financial records and maintaining records of production methods and substances used.

While we believe that an affidavit program is not appropriate at the national level, we do believe that States would be authorized to regulate organic operations exempted under the NOP's $5,000-or-less organic sales exemption under an approved State program. Under this proposal, producers and handlers exempted under the NOP's $5,000-or-less organic sales exemption will be exempt from the certification regulations and will not have to submit an organic system plan to anyone for acceptance or approval but will be required to comply with the requirements for organic production and handling and for labeling. States may implement a program for monitoring the activities of exempt production and handling operations and enforcing compliance with the NOP. States will be permitted to require certification of federally exempted producers and handlers under an approved State organic certification program. The Department will consider any complaint of noncompliance with these regulations by an exempt production or handling operation and take appropriate action.

(5) *Applicability of Federal Statutes.* We have added at § 205.102(c) reference to a production or handling operation's responsibility for complying with all applicable Federal statutes and their implementing regulations as those statutes may apply to the production and handling of agricultural products. We have made this addition as a means of advising producers, handlers, and the public that these regulations do not supersede or alter a producer's or handler's responsibilities under other Federal statutes and their implementing regulations.

A processors association urged the Department to advise the public in this rule that food products produced and processed under the organic standard must comply with applicable provisions of the Federal Food, Drug, and Cosmetic Act; the Federal Meat Inspection Act; the Poultry Products Inspection Act; and all other relevant statutes and their implementing regulations, in all respects, especially related to adulteration and misbranding.

(6) *Recordkeeping Provisions.* We have rewritten the recordkeeping provisions removing all references to specific records or types of records which must be maintained. In their place, we are requiring that certified operations maintain records adapted to the particular business that the certified operation is conducting. Such records must disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited and must be sufficient to demonstrate compliance with the Act and regulations. We have taken this action because we believe that it is impracticable to specify in detail every class of records which may be found essential in demonstrating compliance with the Act and regulations. Different types of certified production and handling operations will, by the very nature of their business, be required to maintain different records to establish their compliance with the Act and regulations.

A certifying agent and a beekeepers association expressed support for the recordkeeping requirements in the first proposal. The beekeeping association emphasized the value of such recordkeeping in monitoring the use of substances. A marketing association and a State commented that the recordkeeping period for a list of substances applied to a certified operation should be changed from 3 to 5 years to be consistent with the requirements of section 6511(d) of the Act. A research foundation suggested removal of the requirement for identifying the name and address of the person who applies and who has applied any substance to any part of the farm and any livestock or other agricultural product. A trade association recommended the addition of a new paragraph addressing the records required to be maintained by crop production operations to establish an audit trail. Specifically, the commenter recommended that the new paragraph require that an audit trail be maintained by all organic crop production operations, which records: (1) All sources and amounts of all off-farm inputs; (2) the dates, rate, method of application, location, reason for use, and name and address of applicator for all off-farm inputs; (3) the dates, projected and actual yield, and harvest location of all crops produced by the operation, both organic and nonorganic; (4) the dates, quantities, and locations of all crops stored; (5) the transport system(s) used to distribute organic crops; and (6) the product name, date, quantity, and buyer of all products sold, both organic and nonorganic. A State commenter stated that the maintenance of records on a certified operation is important, but there must be restraint in requiring redundant or irrelevant information. Approximately 50 retail commenters, speaking on behalf of a producer handler, stated that the recordkeeping requirements were burdensome and overly complicated.

Comments indicated that there was some concern regarding what records had to be maintained by certified operations. Commenters were concerned about requiring the maintenance of the correct records for establishing an audit trail, avoiding the retention of redundant or irrelevant records, and minimizing the burden and complexity of the recordkeeping.

We agree with the commenters who stated that the recordkeeping period for a list of substances applied should be consistent with the 5-year recordkeeping requirements of the Act.

Accordingly, this proposal at § 205.103(b)(3) requires that certified operations maintain all records applicable to their organic operations for not less than 5 years beyond their creation. We disagree with those commenters who called for more specifics relative to what records need to be maintained and agree with those commenters who expressed concern regarding the magnitude of records required to be maintained. This proposal provides each production and handling operation with the opportunity to decide for itself what records are necessary to demonstrate its compliance with the Act and regulations.

(7) *Exemption from Prevention of Commingling.* We have removed the requirement that a handling operation or portion of a handling operation that handles only agricultural products that contain less than 50 percent organic ingredients by total weight of the finished product (excluding water and salt) that is exempt from the requirements in this part comply with the provision for the prevention of commingling. As noted in item 8 below, exempt handlers of agricultural products that contain at least 50 percent organic ingredients by weight will also be exempt from complying with the provision for the prevention of commingling. We have taken this action because the commingling of agricultural products is often a part of the processing activity. Such operations must, however, comply with all of the applicable labeling provisions of subpart D including the prohibition on the combining of organic and nonorganic forms of the same agricultural product. In other words, the handler must not, for example, combine organic and nonorganic corn if corn is to be shown on the information panel as ''organic corn.''

A commenter called for the removal of the requirement that an exempt handler comply with the provisions for the prevention of commingling and contact of organic products with prohibited substances. The commenter claimed that requiring exempt handlers to prevent commingling of organic and nonorganic products and contact of organic products with prohibited substances is inconsistent with the Act. We do not agree. As noted above, we have removed the prevention of commingling requirement because the commingling of agricultural products is often a part of the processing activity. We have not, however, removed the requirement for the prevention of contact of organic products with prohibited substances because the requirement is necessary to safeguard the integrity of organic ingredients used in the products being handled.

(8) *Exemption for Handlers that Handle Product Containing at Least 50 Percent Organic Ingredients.* We have provided at § 205.101(a)(4) that any handling operation or portion of a handling operation that handles agricultural products that contain at least 50 percent organic ingredients by weight (excluding water and salt) that chooses to not use the word, ''organic,'' on any panel other than the information panel is exempt from the requirements in these regulations, except the provisions for prevention of contact of organic products with prohibited substances as set forth in § 205.272, the labeling provisions of § 205.309, and the recordkeeping provisions of § 205.101(c).

A commenter stated that the Department is required under the Act to exempt any handling operation or portion of a handling operation that processes agricultural products that contain at least 50 percent organically produced ingredients by weight (excluding water and salt). We disagree with the commenter. Section 6505(c)(1) of the Act ties the exemption from certification to use of the word, ''organic,'' on the principal display panel. The Secretary, in consultation with the National Organic Standards Board (NOSB) and the Secretary of Health and Human Services, may require certification of any operation that chooses to use the word, ''organic,'' on the principal display panel. This proposal provides that handlers, processing agricultural products that contain at least 50 percent organically produced ingredients by weight (excluding water and salt), who choose to only use the word, ''organic,'' on the information panel are exempt from certification. Handlers processing agricultural products that contain at least 50 percent organically produced ingredients by weight (excluding water and salt) who choose to use the word, ''organic,'' on any other panel, including the principal display panel, must be certified. Use of the word, ''organic,'' on the principal display panel carries with it connotations in the minds of consumers regarding the organic nature of the product which necessitate certification of handlers of such products. Further, requiring certification of handlers of such products is consistent with current industry practice.

Applicability—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Exemptions for Handlers.* Commenters stated that under no circumstances should organic handling operations be exempt from certification. A few environmental organizations, a certifying agent, and an industry association commented that the first proposal exceeded statutory authority by broadening the producer exemption in section 6505(d) of the Act to apply to handlers. An agriculture research and education organization stated that, while the Act does not specifically identify handling operations under the producer exemption, including them is a reasonable and workable interpretation of the Act. The commenter stated that the Act provides an exemption to persons who sell no more than $5,000 annually in value of agricultural products and it sees no reason why the exemption should not include handlers. This commenter also recommended that the NOP develop a new category of exemption of up to $10,000 for on-farm processing. The commenter's recommended exemption would apply to value-added, made-on-site products, such as maple syrup, jams, and relishes, and would allow individuals to combine their production and handling exemptions.

We do not agree with those commenters who stated that the first proposal exceeded statutory authority. The title of the exemption in the Act (section 6505(d)) specifically refers to small farmers. However, the text to the exemption provides, in full, that ''subpart (a)(1) shall not apply to persons who sell no more than $5,000 annually in value of agricultural products.'' ''Person'' is defined in the Act as ''an individual, group of individuals, corporation, association, organization, cooperative, or other entity.'' The Act defines ''agricultural product'' as ''any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption. Handlers are covered by the definition of ''person'' and ''agricultural product'' and are thereby eligible for exemption.

The financial burden of certification is no less for handlers with sales of no more than $5,000 annually than it is for producers with sales of no more than $5,000 annually. Therefore, since the cost of certification is the primary reason for exempting production

operations with sales of no more than $5,000 annually, it is reasonable to also exempt handling operations with sales of no more than $5,000 annually.

This proposal exempts production and handling operations that sell agricultural products as ''organic'' but whose gross agricultural income from organic sales totals $5,000 or less annually. Production and handling operations exempted on the basis of organic sales of $5,000 or less annually are exempt from certification under Subpart E and do not need to submit an organic system plan under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C and the labeling requirements of § 205.309.

Exemptions for production operations and handling operations are separate exemptions. Therefore, a production operation that is also a handling operation, due to its production and sale of processed products, must qualify for each exemption separately. The balance of this paragraph lists exemption eligibility examples. A production operation with gross agricultural income from organic sales totaling $5,000 or less annually will be exempt from certification as an organic production operation. A handling operation with gross agricultural income from organic sales totaling $5,000 or less annually will be exempt from certification as an organic handling operation. A production and handling operation with gross agricultural income from organic production sales totaling $5,000 or less annually and organic handling sales totaling $5,000 or less annually will be exempt from certification as an organic production operation and from certification as an organic handling operation. A production and handling operation with gross agricultural income from organic production sales totaling $5,000 or less annually and organic handling sales totaling more than $5,000 annually will be exempt from certification as an organic production operation only. A production and handling operation with gross agricultural income from organic production sales totaling more than $5,000 annually and organic handling sales totaling $5,000 or less annually will be exempt from certification as an organic handling operation only.

Products marketed by exempt production operations and handling operations cannot be represented as certified organic or display the U.S. Department of Agriculture (USDA) organic seal. Products from exempt operations may not be included as organic ingredients in a multiingredient product produced or processed in a certified operation. We anticipate that this exemption will be used primarily by small market gardeners, hobbyists, and other small producers who sell produce and other agricultural products at farmers markets and roadside stands to consumers within their communities.

(2) *Exceeding $5000 Limit for Exemption.* A few commenters, including a State, raised the concern that an organic operation might not anticipate sales over $5,000 but could exceed its exemption due to a bumper crop or market price increases, putting the operation in violation. The Department believes that once an exempted operation reaches the $5,000 maximum exemption level, it is compelled to seek certification, which it would have to obtain and maintain if it is to continue to sell organic products. A certified organic operation, including one which previously lost its exempt status, could switch from certified to exempt if its size or operations were changed such that it no longer sold more than $5,000 annually in value of agricultural products.

(3) *Certification of Exempt Operations.* A producer interpreted ''exempt'' as meaning that operations exempted from certification could not be certified as an organic operation. This interpretation is not correct. Any production or handling operation, including an exempt operation, which makes application for certification as an organic operation and meets the requirements for organic certification may be certified.

(4) *Increasing the Statutory Limitation of $5000 for Exemption.* In the first proposal, we asked for comments as to whether the $5,000 level for exemption from certification should be raised to $10,000 or to another amount and why an increased amount would be appropriate. Suggested levels ranged from $2,000 to $50,000. The suggested levels and justifications for such levels are not sufficiently consistent for us to recommend that Congress change the $5,000 level.

In addition, we requested data as to the number of operations that may be exempt under the current $5,000 limitation for exemption and the number of operations that may be exempt under any new monetary amount suggested. Comments from the few States responding to the request for data as to the number of operations that may be exempt under the current $5,000 limitation revealed that from one-third to one-half of organic producers in the commenting States would be exempt under the statutorily authorized $5,000 exemption limitation.

(5) *Certification of Retail Operations.* A commenter said the first proposal ignored retail operations which contract with an organic farm to produce organic products with the store's brand on the label. The commenter said the retail operation should be certified because it is responsible if violation occurs in the organic production or handling of the branded product. The commenter is incorrect in suggesting that the retailer would be held responsible for a violation if the violation occurred at the production or handling facility. When a retail operation contracts for the production, packaging, or labeling of organic product, it is the certified production or handling operation that is responsible for meeting the applicable organic production or handling requirements under the Act and these regulations. If a violation occurs in the organic production or handling of the product, the certified production or handling operation retains responsibility for the violation even if the retailer's name is on the label.

(6) *Exemption for Products Containing Less than 50 Percent Organic Ingredients.* Several commenters representing States and organic organizations opposed the exemption of a handling operation or portion of a handling operation that handles only agricultural product containing less than 50 percent organic ingredients. They stated that handling operations creating products with organic ingredients should be certified regardless of the percentage of organic ingredients found in the products they produce. These commenters stated that exemptions from certification undermine audit trails and consumer confidence. Each of these commenters called for removal of the proposed exemption. Another commenter stated that, if a product is less than 50 percent organic, then it is not organic and should not be labeled or sold as such.

We disagree with the comments. Because such products consist of less than 50 percent organic ingredients, handlers may only use the word, ''organic,'' on the information panel of such products to truthfully represent the organic nature of the ingredients. Such handlers must also comply with the recordkeeping provisions of § 205.101(c), the prevention of contact of organic products with prohibited substances provisions of § 205.272, and the labeling provisions of § 205.309.

(7) *Ensuring Organic Ingredients are Not Contaminated.* A commenter asked how the Department would ensure that organic ingredients are not contaminated without certification of the handling operation creating the final

product. Handling operations that handle agricultural products containing less than 50 percent organic ingredients and at least 50 percent organic ingredients that are exempt from certification must maintain records sufficient to: (1) Prove that ingredients identified as organic were organically produced and handled, and (2) verify quantities produced for such ingredients. Such operations are required at § 205.101(c) of this proposal to allow representatives of the Secretary and the applicable State program's governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations.

(8) *Exclusion for Handlers that Receive and Distribute Prepackaged Product.* Commenters raised several issues regarding the exclusion of handlers who receive and distribute prepackaged organic products. At least three certifying agents commented that all retailers should be certified unless they handle only organic product in a ''final, sealed retail container,'' or ''final impermeable containers.'' The commenters are apparently seeking further assurance that nothing is added to the organic product while under control of a distributor or retail operation. Because of the wide variety of organic products and the special needs of some of those products, establishing restrictions on the kind of containers used for transportation could unfairly treat some products and commodity industries. For example, some organic products may require containers which ''breathe'' or allow the exchange of air and outside temperatures. Nonpermeable containers could hasten spoilage of some fresh and processed organic products.

A few certifying agents proposed that distributors and trucking companies which transport agricultural products also should be certified under this part. However, such transportation operations do not carry out the functions specified in the definitions for handler and handling operations. Distributors and trucking companies have traditionally been excluded from requirements of agricultural production regulations. The Act cannot be used to regulate activities or entities beyond its regulatory authorities. In this case, it is the responsibility of producers, handlers, interim handlers, and retailers to meet the requirements of this regulation by ensuring that their contracted shippers and distributors understand, respect, and protect the integrity of the organic products they are transporting.

An organic association requested that proper notification of ''good organic handling practices'' be made to the transportation, trucking, and public warehousing sectors to inform them of their responsibilities. The commenter stated that the notification should include requirements for audit trail records, measures needed to prevent commingling and contamination by prohibited substances. This commenter expressed the belief that excluded handlers should preregister and provide a signed statement of acknowledgment of the requirements. Regarding enforcement of the suggested requirements, this commenter stated that enforcement of the requirements should be funded and administered by existing State and Federal inspection services.

We acknowledge the need for education regarding the requirements of this rule as well as such issues as the handling of organic products. The NOP, in cooperation with the NOSB, will provide educational material to the public regarding the requirements of this rule. Such educational material will include good organic handling practices made available to the transportation, trucking, and public warehousing sectors. However, we disagree with the suggestions calling for preregistration of exempt and excluded handlers and enforcement of the requirements by existing State and Federal inspection services. We believe the suggestions create a burden, on exempt and excluded handlers, the Department, and certifying agents, not justified by the nature of the handling performed.

(9) *Seafood Products.* A marketing institute recommended that the first proposal be revised to address seafood products in a separate seafood section and to include provisions that apply to seafood harvested in the wild. This commenter stated that wild-caught seafood should be allowed to be labeled as organic. A processors association also called for the labeling of wild-caught seafood as organic.

While the first proposal contained no standards solely for aquatic animals in an organic operation, it did contain provisions applicable to their production. The first proposal allowed fish and crustaceans, among other livestock types, to be sold, labeled, or represented as organic if such livestock had been brought into an organic operation no later than the earliest commercially available stage of life. Several commenters suggested that the management of aquatic animals differs sufficiently from mammals and poultry to require separate regulatory provisions. We concur and intend to develop detailed practice standards for specific aquatic animals as discussed further under the production and handling subpart.

Applicability—Additional Provisions

Upon further review of the applicability provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *Foreign Applicants.* We have added a new provision at § 205.104 addressing applicability of these regulations to foreign applicants. We have made this addition to clarify our intent that the regulations in this part apply equally to domestic and foreign applicants for accreditation, accredited certifying agents, domestic and foreign applicants for certification as organic production or handling operations, and certified organic production and handling operations unless otherwise specified in these regulations.

(2) *New Exclusions.* We have excluded retail food establishments that process or prepare raw and ready-to-eat food from most of the requirements in these regulations. An excluded retail food establishments must comply with the requirements for the prevention of contact with prohibited substances provisions of § 205.272 and the labeling provisions of § 205.309. We have excluded such retail food establishments because comments to the first proposal concerning the issue of certification of retail food establishments (restaurant, delicatessen, bakery, grocery store, or other retail outlet) preparing, packaging, or processing raw and ready-to-eat organic agricultural products that are previously labeled as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients)'' were completely divergent. The first proposal also contained an inconsistency which would have required a supermarket delicatessen to be certified but would have excluded from certification a restaurant with carry-out delicatessen products.

As the comments discussed below show, there is clearly a great deal of public concern regarding the handling of organic products by retail food establishments. Should we decide to regulate retail food establishments under the NOP, we will proceed with rulemaking and provide an opportunity for public comment.

Our exclusion of retail food establishments from this proposal does not prevent a State from developing an organic retail food establishment certification program or otherwise regulating retail food establishments that prepare, package, or process organic

agricultural products. Texas and Maryland currently have retailer certification programs.

No retailer, regardless of this exclusion and the exceptions found in the definitions for ''handler'' or ''handling operation,'' may sell or label a product as organically produced and handled or fix a label to or provide other market information concerning an agricultural product if such label or information implies that such product is produced and handled using organic methods unless such product has been produced and handled in accordance with the Act and these regulations. Any retailer who knowingly sells or labels a product as organic, except in accordance with the Act and these regulations, will be subject to a civil penalty of not more than $10,000 under this program. Such retailer may also be subject to enforcement actions and penalties under Federal statutes and their implementing regulations administered by other agencies of the Federal Government.

More than 90 commenters, including an organic association, stated that the retailer exclusion in the first proposal violates the requirement to certify all handling operations. The organic association believes that processing, as defined in the Act, includes all the normal culinary arts, food manufacturing, and packaging. All of these commenters, including some States, recommended removal of the exclusion. Several commenters, including a few States, expressed concern that exclusions from certification eliminate effective audit trails and undermine consumer confidence in organic products. One State commented that it believed retail food establishments should be certified because they are the last handler link from producer to consumer.

Several commenters stated that retailers who receive organic product have a high potential for loss of integrity of the organic product due to accidental misuse of pesticides and sanitizers during shipping or storage and to inadvertent commingling with nonorganic product. The commenters believe that, even though a retailer may only display and sell organic product, such retailer should be certified and monitored for compliance to ensure proper treatment of the product in shipment and storage. A State agency, however, cautioned against establishing another burden on the organic industry. The commenter said that if sorting from bulk and repackaging into smaller packages requires certification, then many small ''natural food'' retail outlets would find certification more costly than the economic benefits of marketing organic products. The commenter said many small, natural food retail food establishments would likely stop carrying organic items.

A few commenters stated there is a high potential for fraud among retailers who have the opportunity to repackage, mislabel, and sell nonorganic product as organic. Therefore, they believe that all retailers must be subject to certification or some form of oversight to assure that they are not mislabeling product.

A commenter representing a large retail grocery store operation said that good identification procedures enable retail stores to keep organic product separated from nonorganic product during transportation, storage, and in-store displays. The commenter continued that unduly rigid requirements would be burdensome on retailers. The commenter indicated that the costs of certification and compliance may outweigh the benefits of carrying organic product.

Another commenter from a major retail food establishment suggested that retailers that wash and sort fresh organic produce for display should be required to follow ''good organic handling practices'' that would establish recordkeeping responsibilities and prevent commingling with nonorganic products and contamination by prohibited materials. The commenter suggested that conformance could be maintained by existing State or local health inspectors or Federal inspectors with special training in organic handling systems. However, there is no authority in the Act to require the services of State or local inspectors.

Another retailer stated that retailers will comply with regulations because consumers will hold retailers responsible for deficiencies or illegal actions through the entire production and processing chain for agricultural products.

A commenter stated that, if a restaurant serves organic foods, it should be allowed to so state. The commenter went on to say that restaurants and grocery stores have a right to state that they used organic ingredients in preparing a given dish. This commenter believes that restaurants and grocery stores selling organic products, even if they prepare them, should not have to be certified. A few commenters claimed that processing, as defined in the Act, includes all culinary arts and food manufacturing. They stated that restaurants must be certified or, at the very least, be required to keep records of organic foods prepared. A State commenter who stated that exemptions undermine audit trails and consumer confidence suggested that restaurants serving organic foods be required to maintain records showing the origin and certification status of raw agricultural ingredients used in the restaurant's food products.

The Department routinely monitors compliance of various food producers, handlers, distributors, and retailers which are regulated under a variety of Departmental programs. The Department responds to consumer complaints and often conducts unannounced compliance investigations and audits of agricultural industry businesses. The Department understands the need for and commits Departmental resources to this organic program. In addition, oversight of these operations can be conducted by State agencies.

Subpart C—Organic Crop, Wild Crop, Livestock, and Handling Requirements

Proposal Description

This subpart sets forth the requirements with which production and handling operations must comply in order to sell, label, or represent agricultural products as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients).'' The producer or handler of an organic production or handling operation must comply with all applicable provisions of subpart C. Any practice implemented in accordance with this subpart must maintain or improve the natural resources, including soil and water quality, of the operation. Production and handling operations which sell, label, or represent agricultural products as organic in any manner and which are exempt or excluded from certification must comply with the requirements of this subpart, except for the development of an organic system plan.

Production and Handling (General). The Organic Food Production Act of 1990 (OFPA or Act) requires that all crop, wild crop, livestock, and handling operations requiring certification submit an organic system plan to their certifying agent and, where applicable, the State organic program. The organic system plan is a detailed description of how an operation will achieve, document, and sustain compliance with all applicable provisions in the OFPA and these regulations. The certifying agent must concur that the proposed organic system plan fulfills the requirements of Subpart C, and any subsequent modification of the organic plan by the producer or handler must receive the approval of the certifying agent.

The organic system plan is the forum through which the producer or handler and certifying agent collaborate to define, on a site-specific basis, how to achieve and document compliance with the requirements of certification. The organic system plan commits the producer or handler to a sequence of practices and procedures resulting in an operation that complies with every applicable provision in the regulations. Accreditation qualifies the certifying agent to attest to whether an organic system plan comports with the organic standard. The organic system plan must be negotiated, enacted, and amended through an informed dialogue between certifying agent and producer or handler, and it must be responsive to the unique characteristics of each operation.

An organic system plan contains six components. First, the organic system plan must describe the practices and procedures used, including the frequency with which they will be used, in the certified operation. Second, it must list and characterize each substance used as a production or handling input. Third, it must identify the monitoring techniques which will be used to verify that the organic plan is being implemented in a manner which complies with all applicable requirements. Fourth, it must explain the recordkeeping system used to preserve the identity of organic products from the point of certification through delivery to the customer who assumes legal title to the goods. Fifth, the organic system plan must describe the measures to be taken to avoid contact between certified production and handling operations and prohibited substances and document how the operation will prevent commingling of organic and nonorganic products. Finally, the organic system plan must contain the additional information deemed necessary by the certifying agent to evaluate site-specific conditions relevant to compliance with these or applicable State program regulations. Producers or handlers may submit a plan developed to comply with other Federal, State, or local regulatory programs if it fulfills the requirements of an organic system plan.

The first element of the organic system plan requires a narrative or other descriptive format that identifies the practices and procedures to be performed and maintained, including the frequency with which they will be performed. Practices are tangible production and handling techniques such as the method for applying manure, the mechanical and biological methods used to prepare and combine ingredients and package finished products, and the measures taken to exclude pests from a facility. Procedures are the protocols established for selecting appropriate practices and materials for use in the organic system plan, such as a procedure for locating commercially available organically produced seed. Procedures reflect the decision-making process used to implement the organic system plan.

By requiring information on the frequency with which production and handling practices and procedures will be performed, this proposal calls for the organic system plan to include an implementation schedule, including information on the timing and sequence of all relevant production and handling activities. The plan will include, for example, information about planned crop rotation sequences, the timing of any applications of organic materials, and the timing and location of soil tests. Livestock management practices might describe development of a rotational grazing plan or addition of mineral supplements to the feed supply. A handling operation might identify steps involved in locating and contracting with farmers who could produce organic ingredients that were in short supply.

The second element that must be included in an organic system plan is information on the application of substances to land, facilities, or agricultural products. This requirement encompasses both natural and synthetic materials allowed for use in production and handling operations. For natural materials which may be used in organic operations under specific restrictions, the organic plan must detail how the application of the materials will comply with those restrictions. For example, farmers who apply manure to their fields must document in their organic system plans how they will prevent that application from contributing to water contamination.

The third element of the organic system plan is a description of the methods used to evaluate its effectiveness. Producers and handlers are responsible for identifying measurable indicators that can be used to evaluate how well they are achieving the objectives of the operation. For example, production objectives could be measured through regular tallies of bushels or pounds of product sold from the farm or in numbers of cases sold from a handling operation. Indicators that can identify changes in quality or effectiveness of management practices could be relatively simple, such as the information contained in a standard soil test. The specific indicators used to evaluate a given organic system plan will be determined by the producer or handler in consultation with the certifying agent. Thus, if the organic system plan calls for improvements in soil organic matter content in a particular field, it would include provisions for analyzing soil organic matter levels at periodic intervals. If herd health improvement is an objective, factors such as somatic cell count or observations about changes in reproductive patterns might be used as indicators.

The fourth element of the organic system plan is a description of the recordkeeping system used to verify and document an audit trail, as appropriate to the operation. For each crop or wild-crop harvested, the audit trail must trace the product from the field, farm parcel, or area where it is harvested through the transfer of legal title. A livestock operation must trace each animal from its entrance into through removal from the organic operation. A handling operation must trace each product that is handled and sold, labeled, or represented as organic from the receipt of its constituent ingredients to the sale of the processed product. In response to several comments received, this proposal provides information, found in subpart B, § 205.103, on the records needed to establish a verifiable audit trail.

The fifth element which must be included in an organic system plan pertains to split production or handling operations. This provision requires an operation that produces both organic and nonorganic products to describe the measures used to prevent commingling of organic and nonorganic products. This requirement addresses contact of organic products, including livestock, organic field units, storage areas, and packaging to be used for organic products, with prohibited substances. Requirements in the first proposal for information about the nonorganic portion of the operation have been removed.

We do not propose to list the specific requirements to be included in an organic system plan. We expect to publish a program manual to provide guidance on appropriate documentation for the certification process. In the meantime, the accreditation process provides an assurance that certifying agents are competent to determine the specific documentation they require to review and evaluate an operation's organic system plan. Section 205.200(a)(6) allows a certifying agent to request additional information needed to determine that an organic system plan meets the requirements of this

subpart. The site-specific nature of organic production and handling necessitates that certifying agents have the authority to determine whether specific information is needed to carry out their function.

Crop Production. Any field or farm parcel used to produce an organic crop must have been managed in accordance with the requirements in §§ 205.203 through 205.206 and have had no prohibited substances applied to it for at least 3 years prior to harvest of the crop. Such fields and farm parcels must also have distinct, defined boundaries and buffer zones to prevent contact with the land or crop by prohibited substances applied to adjoining land.

A producer of an organic crop must manage soil fertility, including tillage and cultivation practices, in a manner that maintains or improves the physical, chemical, and biological condition of the soil and minimizes soil erosion. Crop nutrients must be budgeted and supplied through proper use of manure or other animal and plant materials, mined mineral substances, and other substances approved for use under these regulations. The producer must manage animal and plant waste materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Raw animal manure must either be composted, applied to land used for a crop not intended for human consumption, or incorporated into the soil at least 90 days before harvesting an edible product that does not come into contact with the soil or soil particles and at least 120 days before harvesting an edible product that does come into contact with the soil or soil particles. Composted plant or animal waste materials used for soil fertility must be produced in compliance with the Natural Resources Conservation Service's (NRCS) Conservation Practice Standard for a Composting Facility (Code 317). Uncomposted plant and animal waste materials may be used to amend soil fertility. A plant or animal waste material that has been chemically altered by a manufacturing process may be used only if it is included on the National List of synthetic substances allowed for use in organic production. Mined substances of low solubility may be used as sources of crop nutrients, as may mined substances of high solubility, when justified by soil or crop tissue analysis. Ashes of untreated plant or animal materials which have not been combined with a prohibited substance and which are not included on the National List of nonsynthetic substances prohibited for use in organic crop production may be used to produce an organic crop. Synthetic crop nutrient supplements that appear on the National List of allowed synthetic substances may be used as a source of crop nutrients when justified by soil or crop tissue analysis. The producer may not use any fertilizer that contains a synthetic substance not allowed for crop production on the National List or use sewage sludge. Burning crop residues as a means of disposal, except for trimmings of perennial crops burned to suppress the spread of disease, is prohibited.

The producer must use organically grown seeds, annual seedlings, and planting stock, except that untreated nonorganic seeds and planting stock may be used when equivalent organic varieties are not commercially available. Seed and planting stock treated with substances that appear on the National List of synthetic substances allowed for use in organic production may be used when an organically produced or untreated variety is not commercially available. Nonorganically produced annual seedlings may be used when a temporary variance has been established due to damage caused by unavoidable business interruption, such as fire, flood, or frost. Planting stock used to produce a perennial crop may be sold as organically produced planting stock after it has been maintained under a system of organic management for at least 1 year. Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the substance is a requirement of Federal or State phytosanitary regulations. Seeds, annual seedlings, or planting stock produced through an excluded method may not be used for organic production.

The producer is required to implement a crop rotation, including but not limited to sod, cover crops, green manure crops, and catch crops. The crop rotation must maintain or improve soil organic matter content, provide for effective pest management in perennial crops, manage deficient or excess plant nutrients, and control erosion to the extent that these functions are applicable to the operation.

The producer must use preventive practices to manage crop pests, weeds, and diseases, including but not limited to crop rotation, soil and crop nutrient management, sanitation measures, and cultural practices that enhance crop health. Such cultural practices include the selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases. Mechanical and biological methods that do not entail application of synthetic substances may be used as needed to control pest, weed, and disease problems that may occur. Pest control practices include augmentation or introduction of pest predators or parasites; development of habitat for natural enemies; and nonsynthetic, nontoxic controls such as lures, traps, and repellents. Weed management practices include mulching with fully biodegradable materials; mowing; livestock grazing; hand weeding and mechanical cultivation; flame, heat, or electrical techniques; and plastic or other synthetic mulches, provided that they are removed from the field at the end of the growing or harvest season. Disease problems may be controlled through management practices which suppress the spread of disease organisms and the application of nonsynthetic biological, botanical, or mineral inputs. When these practices are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance, or a synthetic substance that is allowed on the National List may be used provided that the producer evaluates and mitigates the effects of repetitive use of the same or similar materials on resistance and shifts in pest, weed, or disease types. The producer must use a pest, weed, or disease control substance in compliance with the Federal Insecticide, Fungicide, and Rodenticide Act. Pest control substances produced through excluded methods are prohibited.

Any wild crop that is to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients)'' must be harvested from land to which no prohibited substances have been applied for at least 3 years prior to harvest. The wild crop must also be harvested in a manner that ensures such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

Livestock Production. We propose that any livestock or edible livestock product to be sold, labeled, or represented as organic must be maintained under continuous organic management from birth or hatching, with four exceptions. Poultry or edible poultry products must be from animals that have been under continuous organic management beginning no later than the second day of life. Milk or milk products must be from animals that

have been under continuous organic management beginning no later than 1 year prior to the production of such products. A nonedible livestock product must be derived from an animal that has been under continuous organic management beginning no later than 1 year prior to the harvest of the nonedible product. Livestock used as breeder stock may be brought from a nonorganic operation into an organic operation at any time, provided that, if such livestock are gestating and the offspring are to be organically raised from birth, the breeder stock must be brought into the organic operation prior to the last third of pregnancy.

We also propose that, should an animal be brought into an organic operation pursuant to this section and subsequently moved to a nonorganic operation, neither the animal nor any products derived from it may be sold, labeled, or represented as organic. Breeder or dairy stock that has not been under continuous organic management from birth may not be sold, labeled, or represented as organic slaughter stock. No organism produced with excluded methods may be used for breeding purposes or for the production of livestock products intended to be sold, labeled, or represented as organic. The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed livestock and all edible and nonedible organic livestock products produced on his or her operation.

We are proposing that, except for feed additives and supplements included on the National List of synthetic substances allowed for use in organic livestock production, the total feed ration for livestock managed in an organic operation must be composed of agricultural products, including pasture and forage, that are organically produced. Any portion of the feed ration that is handled must comply with organic handling requirements. The producer must not use animal drugs, including hormones, to promote growth in an animal or provide feed supplements or additives in amounts above those needed for adequate growth and health maintenance for the species at its specific stage of life. The producer must not feed animals under organic management plastic pellets for roughage or formulas containing urea or manure. The feeding of mammalian and poultry slaughter by-products to mammals or poultry is prohibited. The producer must not supply animal feed, feed additives, or feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.

The producer of an organic livestock operation must establish and maintain preventive animal health care practices. The producer must select species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites. The producer must provide organic feedstuffs, as well as vitamins, minerals, and other supplements, sufficient to meet the animals' nutritional requirements. The producer must establish appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites. Animals in an organic livestock operation must be maintained under conditions which provide for exercise, freedom of movement, and reduction of stress appropriate to the species. Additionally, all physical alterations performed on animals in an organic livestock operation must be conducted to promote the animals' welfare and in a manner that minimizes stress and pain.

The producer of an organic livestock operation must administer vaccines and other veterinary biologics as needed to protect the well-being of animals in his or her care. When preventive practices and veterinary biologics are inadequate to prevent sickness, the producer may administer medications included on the National List of synthetic substances allowed for use in livestock operations. The producer may not administer synthetic parasiticides to breeder stock during the last third of gestation if the progeny is to be sold, labeled, or represented as organically produced. After administering synthetic parasiticides to dairy stock, the producer must observe a 90-day withdrawal period before selling the milk or milk products produced from the treated animal as organically produced. Every use of a synthetic medication or parasiticide must be incorporated into the livestock operation's organic system plan subject to approval by the certifying agent.

We propose that the producer of an organic livestock operation must not treat an animal in that operation with antibiotics, any synthetic substance not included on the National List of synthetic substances allowed for use in livestock production, or any substance that contains a nonsynthetic substance included on the National List of nonsynthetic substances prohibited for use in organic livestock production. The producer must not administer any animal drug, other than vaccinations, in the absence of illness. The use of hormones is prohibited in organic livestock production, as is the use of synthetic parasiticides on a routine basis. The producer must not administer synthetic parasiticides to slaughter stock or administer any animal drug in violation of the Federal Food, Drug, and Cosmetic Act. The producer must not withhold medical treatment from a sick animal to maintain its organic status. All appropriate medications and treatments must be used to restore an animal to health when methods acceptable to organic production standards fail. Livestock that are treated with prohibited materials must be clearly identified and shall not be sold, labeled, or represented as organic.

Under this proposal, a livestock producer must document in his or her organic system plan the preventative measures he or she has in place to deter illness, the allowed practices he or she will employ if illness occurs, and his or her protocol for determining when a sick animal must receive a prohibited animal drug. The standards we are proposing will not allow an organic system plan that envisions an acceptable level of chronic illness or proposes to deal with disease by sending infected animals to slaughter. Neither situation can be considered consistent with the principles of organic management. The organic system plan must reflect a proactive approach to health management, drawing upon allowable practices and materials. Animals with conditions that do not respond to this approach must be treated appropriately and diverted to nonorganic markets.

The producer of an organic livestock operation must establish and maintain livestock living conditions for the animals under his or her care which accommodate the health and natural behavior of the livestock. The producer must provide access to shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment. This requirement includes access to pasture for ruminant animals. The producer must also provide appropriate clean, dry bedding, and, if the bedding is typically consumed by the species, it must comply with applicable organic feed requirements. The producer must provide shelter designed to allow for the natural maintenance, comfort level, and opportunity to exercise appropriate to the species. The shelter must also provide the temperature level, ventilation, and air circulation suitable to the species and reduce the potential for livestock injury. The producer may provide temporary confinement of an animal because of inclement weather; the animal's stage of production;

conditions under which the health, safety, or well-being of the animal could be jeopardized; or risk to soil or water quality. The producer of an organic livestock operation is required to manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes nutrient recycling.

Handling. This proposal permits mechanical or biological methods to be used to process an agricultural product intended to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients)'' for the purpose of retarding spoilage or otherwise preparing the agricultural product for market. It permits the use of nonagricultural substances and nonorganically produced agricultural products that are included on the National List in or on a processed agricultural product intended to be sold, labeled, or represented as ''organic'' or ''made with organic (specified ingredients).'' This proposal prohibits a handler from using ionizing radiation for any purpose, an ingredient produced with excluded methods, or a volatile synthetic solvent in or on a processed agricultural product intended to be sold, labeled, or represented as ''100 percent organic,'' ''organic,'' or ''made with organic (specified ingredients).''

The practice standard for facility pest management requires the producer or handler operating a facility to use management practices to prevent pests, including removing pest habitat, food sources, and breeding areas; preventing access to handling facilities; and controlling environmental factors, such as temperature, light, humidity, atmosphere, and air circulation to prevent pest reproduction. Permitted pest control methods include augmentation or introduction of predators or parasites for the pest species; mechanical or physical controls, including traps, light, or sound; and nontoxic, nonsynthetic controls, such as lures and repellents.

This proposal permits the use of a nonsynthetic biological or botanical substance or any synthetic substance to control facility pests if the permitted prevention and control practices are not effective. Any substance applied must be used in accordance with the label provisions as approved by the appropriate authority, such as the Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA). We propose that the handler of an organic handling operation who uses any biological, botanical, or synthetic substance to control facility pests must specify in the organic system plan all measures taken or intended to be taken to prevent contact between the substance and any ingredient or finished product intended to be sold, labeled, or represented as organic or made with organic ingredients. In addition to these restrictions, the handler must include in the organic handling plan an evaluation of the effects of repetitive use of the same or similar materials on pest resistance and shifts in pest types.

This proposal delineates practice standards that must be followed by an organic handling operation to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances. An organic handling operation must not use packaging materials and storage containers or bins that contain a synthetic fungicide, preservative, or fumigant in handling an organic product. The operation also must not use or reuse any storage bin or container that was previously in contact with any prohibited substance unless the reusable bin or container has been thoroughly cleaned and poses no risk of prohibited materials contacting the organic product.

Temporary Variances. This subpart establishes conditions under which operations may receive temporary variances from the provisions contained in §§ 205.203 through 205.207, 205.336 through 205.239, and 205.270 through 205.272. The Administrator may establish temporary variances due to natural disasters declared by the Secretary; unavoidable business interruption caused by catastrophe such as wind, fire, hail, flooding, excessive moisture, earthquake, or drought; or to conduct research on organic production and handling techniques or inputs. A certifying agent may recommend that the Administrator establish a temporary variance for unavoidable business interruption. The Administrator will determine how long a temporary variance will be in effect at the time it is established, subject to extension as the Administrator deems necessary. Upon notification by the Administrator that a temporary variance has been established due to a natural disaster, a certifying agent must inform each production and handling operation it certifies within the affected geographical region or each individual production and handling operation affected by the temporary variance. Temporary variances may not be issued for any practice, material, or procedure which is otherwise prohibited by these regulations.

A request for issuance of a temporary variance, the justification for it, and measures to evaluate the impact of the practice on the operation's natural resources must be documented in the organic plan and approved by the certifying agent. For example, if a drought resulted in a severe shortage of organically produced hay, a dairy operation might be permitted to substitute some nonorganic hay for a portion of the herd's diet to prevent liquidation of the herd. The producer must keep records showing the source and amount of the hay and update the organic plan to describe the justification for the practice and a timeframe for restoring the total feed ration to organic sources. The certifying agent might also request that the plan include contingency measures to avoid the need to resort to nonorganic feed in case of a future shortage. A variance for experimental purposes might be issued to permit a crop producer to undertake on-farm trials of small quantities of a new (but not produced with excluded methods) crop variety that was not available as organic seed.

Production and Handling (General)—Changes Based on Comments

The subpart differs from our first proposal in several respects as follows:

(1) *Genetically Engineered Organisms.* In the first proposal, we invited public comment on the use of genetically engineered organisms (GEO's) or their products in a system of organic production and handling. Specifically, we asked whether the use of GEO's or their products should be permitted, prohibited, or allowed on a case-by-case basis in organic production or handling operations. Hundreds of thousands of public comments opposed the use of GEO's or their products in organic production or processing. In response to these comments, this proposal prohibits use of genetic engineering (included in the broad definition of ''excluded methods'' in this proposal, based on the definition recommended by the National Organic Standards Board (NOSB)) in all stages of organic production and handling. This proposal contains a specific prohibition on the use of seeds, annual seedlings and planting stock (§ 205.204(b)), pest control substances (§ 205.206(f)), organisms (§ 205.236 (b)(3)), and ingredients (§ 205.270(c)(2)) produced with excluded methods.

Products created with modern biotechnology techniques have been tested, approved by the appropriate regulatory agencies, and can be used safely in general agricultural production. At the same time,

consumers have made clear their opposition to use of these techniques in organic food production. This rule is a marketing standard, not a safety standard. Since use of genetic engineering in the production of organic foods runs counter to consumer expectations, foods produced through excluded methods will not be permitted to carry the organic label.

We acknowledge that the broad prohibition on use of excluded methods in organic production and handling systems may create compliance obstacles for organic operations and certifying agents. For example, many current certification programs allow vaccination of animals with synthetic compounds when such treatment is mandatory. However, while many FDA-approved vaccines are now produced using excluded methods, we are unaware of any certification program which has an enforcement mechanism to ensure that such substances are not used in organic production. We do not know to what extent, if any, organic livestock producers are currently using vaccines produced with excluded methods or how a prohibition on the use of such substances would affect development of the industry.

Similarly, the prohibition on the use of excluded methods in the production of organic foods may also present challenges to organic handlers and certifying agents. This may pose a particular problem with respect to the nonorganic ingredients of multiingredient products with 50-95 percent organic content, to which the prohibition on use of excluded methods also applies. For example, it may be harder for organic food processors, who may struggle to find sources of nonorganic ingredients that are produced without use of excluded methods and for certifying agents, who must ensure that handlers have complied with this requirement.

As with most elements of this program, compliance monitoring and enforcement will rely on the ongoing oversight of organic operations by USDA-accredited certifying agents, rather than on product testing. Certifying agents must approve organic plans that detail procedures and practices to be followed by organic operations and will review extensive records maintained by organic operations to ensure that they are complying with the approved organic plans and the regulations.

This system of compliance assurance will be particularly important with respect to the prohibition on use of excluded methods. Producers and handlers must be vigilant in the acquisition of materials and products. Certifying agents should be aware of agricultural products produced through excluded methods and must carefully review material and product origin documentation. It will be the responsibility of certifying agents to review the sourcing specifications and other provisions of producer and handler organic plans to ensure the integrity of organic and multiingredient products. We anticipate that this system of carefully reviewed and documented organic plans, which establishes documented procedures demonstrating good faith efforts to diligently pursue and maintain the integrity of ingredients produced without use of excluded methods, could satisfy the requirements in this regulation.

With respect to the prohibition on the use of excluded methods in production of the nonorganic ingredients in multiingredient products, we recognize that the ability to meet these requirements depends primarily on practices used in conventional agricultural markets. We also recognize that practices for preserving product identity, including segregating genetically engineered and nongenetically engineered products, are evolving in some conventional markets. Currently there are no consensus industry standards for product segregation, rather contractual agreements are used to the extent possible. As the marketplace evolves toward recognized best practices or standards for product testing and segregation, we anticipate that these methods and systems will become the standards for implementing the prohibition on use of excluded methods in production of nonorganic ingredients in multiingredient products. Linking the requirements pertaining to nonorganic ingredients in this proposal to the evolving practices within the marketplace will provide certifying agents with a verifiable criterion against which to evaluate production and handling processes, as well as providing greater certainty to handlers and processors as they seek to identify acceptable sources of nonorganic ingredients.

As with other prohibited substances, a positive detection of a product of excluded methods would trigger an investigation by the certifying agent to determine if a violation of organic production or handling standards occurred and would not necessarily represent a violation on its own. The presence of a detectable residue alone does not necessarily indicate use of a product of excluded methods that would constitute a violation of the standards.

We anticipate that these issues will be of particular interest to commenters on the proposal, and that comments may help to shed light on industry capabilities and expectations. We recognize that this policy will place additional burdens on certified operations and certifying agents, but we believe that the necessity to meet strong consumer expectations outweighs these concerns.

(2) *Measurable Degradation Standard.* We are proposing that any practice implemented in accordance with the requirements for organic production and handling must maintain or improve the soil and water quality of the operation. This provision is a modification of the requirement in the first proposal that the use or application of a practice not result in measurable degradation of soil or water quality. Some commenters stated that the concept of measurable degradation was too limiting and reduced the holistic principles behind organic production to an exercise in risk assessment. In introducing the concept of measurable degradation, we stated that its purpose was to ''clarify that all methods and substances used in an organic operation shall be consistent with a system of organic farming and handling and the purposes of the OFPA.'' As such, measurable degradation and the specific indicators of soil and water quality used to monitor it were designed as tools to evaluate compliance with the OFPA and not as ends in themselves.

The new provision requiring that an organic operation maintain or improve its soil and water quality retains the linkage between production and handling practices and the natural resources of the operation, which is a fundamental tenet of both organic production and the OFPA. We have introduced the ''maintain or improve'' provision to allow for consideration of a variety of environmental indicators that contribute to the overall performance of the operation. Both the objective of certification—establishing an organic system of production and handling—and the standard by which it is achieved—the requirements in this proposal—remain constant for all operations. The environmental indicators used to establish and monitor compliance with an approved organic system plan will depend upon the site-specific conditions of the individual operation. For example, a producer and certifying agent would consider the soil types, hydrology, other environmental conditions and the specific nature of the crops and livestock being produced to

determine which indicators would best reflect the performance of the organic system plan. Site-specific conditions—high water table, soils that are prone to erosion—combined with the operation's production practices—the use of persistent inputs such as copper or sulfur compounds, the type of tillage practices used—will dictate the selection of environmental indicators. While individual indicators, especially when signaling that significant change has occurred, remain important, the ''maintain or improve'' provision allows a producer or handler and his or her certifying agent to assume a broader perspective in monitoring compliance with the OFPA.

Many commenters objected to the requirement in the first proposal that certain production practices ''not result in a measurable degradation of the soil.'' The purpose of the ''measurable degradation'' requirement was solely to provide producers and their certifying agents with quantifiable, verifiable tools with which to evaluate compliance with the applicable regulations. While the current proposal does not refer to ''measurable degradation'' in the practice standards, producers and handlers must identify and incorporate into their organic system plans specific testing and evaluation techniques to measure the environmental impact of their production practices. In many cases, this requirement could be filled with a standard soil analysis, which would indicate trends in soil organic content, nutrient composition, and physical properties. In other cases, chemical or biological analysis of stream water entering and leaving a crop or livestock operation could suffice to monitor compliance with the practice standards. There is no way to substantiate the effectiveness of the practices and materials used in an organic production system without some form of measurable verification. Analytical procedures to monitor the condition, over time, of an operation's resource base are a standard feature of efficient resource management, whether or not the operation is organically managed.

(3) *Function and Content Requirements of the Organic System Plan.* We propose significant changes in the function and content requirements of the organic system plan to solidify its role in the relationship between producer or handler and certifying agent. Public comment on the first proposal identified numerous perceived deficiencies in the provisions for an organic system plan. Some commenters, including organic certifying agents and industry associations, stated that the proposed content requirements were a ''shadow'' of the plan intended by the OFPA because the regulatory text did not include the words, ''management,'' ''rotation,'' or ''manure.'' Some commenters characterized the organic system plan in the first proposal as a simple list of materials to be used and practices to be followed and thought that it would not adequately address why the producer or handler made specific production choices. Echoing the recommendation adopted by the NOSB at its June 1994 meeting in Santa Fe, NM, other commenters suggested that each organic system plan should be required to include key elements of organic production, such as soil and crop management, resource conservation, crop protection, and maintenance of organic integrity through growing, harvesting, and postharvest operations. We fully agree with the principle that a comprehensive organic system plan is an integral component of a certified operation and that it provides the foundation for the working relationship between the certifying agent and the producer or handler. This proposal contains a standard that defines and characterizes an organic system of production and handling and establishes the organic system plan as the centerpiece of the relationship between producer or handler and certifying agent.

Some commenters expressed concern that the first proposal did not link the organic system plan to specific regulatory requirements such as proper tillage, crop rotation, and manuring. The first proposal did, however, require operations to document compliance with all applicable standards. The obligation to document compliance with all applicable standards was implicit in the requirement that an organic system plan contain a description of the practices to be performed and maintained to establish a system of organic farming and handling. A producer or handler intending to engage in a practice must comply with the corresponding standards and include his or her intentions for doing so in the organic system plan. This proposal contains a similar provision, found in § 205.200(a)(1), which requires a description of the practices and procedures used in the certified operation, again, without stating the specific standards with which the operation must comply.

We acknowledge that, by providing the regulatory guidance necessary to implement the OFPA, the Secretary is further empowering accredited certifying agents to determine whether an operation's organic system plan meets the requirements of the statute. The provisions for an organic system plan in § 205.200(a)(1)–(6) outline the prerequisites for certification. Combined with the production and handling standards in §§ 205.201 through 205.207, 205.236 through 205.239, and 205.270 through 205.272, these requirements provide the criteria necessary for certifying agents to determine whether to grant certification.

For similar reasons, we propose not to include in this proposal a list of the specific requirements to be included in a particular type of organic system plan. For example, while the first proposal required that a farm operation submit the total acreage under organic management as part of its organic system plan, there is no similar requirement in this proposal. We believe that accredited certifying agents are capable of determining the specific documentation they require to review an application for certification. Certifying agents are granted authority to request the information they deem essential to the performance of their duties. Many resources are available to certifying agents for determining the information needed to make certification decisions. The Federal-State Marketing Improvement Program of the Agricultural Marketing Service (AMS) helped fund a project (#12–25–G–0202) which created an organic inspection manual and developed a whole set of organic certification form templates. Among these templates are detailed forms for organic farm, livestock, and handling system plans. AMS worked with the Independent Organic Inspectors Association and the Organic Certifiers Council on this project and supports continued movement toward standardized certification documentation. The NOSB provided recommendations, including sample questionnaires, for the information it deems necessary for inclusion in an organic system plan. Additionally, the Organic Trade Association recently released the American Organic Standards that drew upon broad industry involvement to create a detailed description of organic system plan requirements.

The organic system plan in the first proposal included requirements for split farming operations—meaning farms that engage in both organic and nonorganic production—that some commenters stated were excessive. These commenters pointed out that the OFPA does not provide for the organic system plan to include any production or handling practice not consistent with the OFPA, and that the practices on the nonorganic portion of the split-farm

would not be consistent with the Act. Based on these comments, this proposed organic production system plan will not require information about a split-farm's nonorganic operations. However, this proposal requires that a split operation, whether a production or a handling operation, describe the measures it is taking or will take to prevent commingling of organic and nonorganic product and to prevent contact of organic products, fields, or facilities with prohibited substances.

(4) *Regulatory Enforcement.* The National Organic Program (NOP) will require consistent and effective enforcement of the regulations across diverse crop, wild crop, livestock, and handling operations which are differentiated by site-specific conditions within dissimilar geographic regions. The resources and objectives of each certified operation are unique, and the OFPA, accordingly, provides certifying agents with criteria, not formulas, to determine whether the practices, procedures, and inputs described in an organic system plan constitute compliance with the OFPA. The flexibility implicit in this approach allows producers and handlers to choose from a variety of production and handling options. In addition to being flexible, a regulatory mechanism must be clear, consistent, and enforceable. For this reason, producers and handlers must document the choices they make in an organic system plan and demonstrate a good-faith effort to implement the plan. For example, the decision to use an allowed synthetic pest control substance must be based on evidence that prevention and nonsynthetic pest control measures are not adequate.

Public comment indicated that the regulatory mechanisms that were introduced in the first proposal, including orders of preference, performance standards, and provision for allowance of certain practices ''if necessary,'' provided producers and handlers too much discretion in selecting materials and practices. These comments indicated that insufficient oversight by certifying agents could dilute the meaning of organic certification. Therefore, we are proposing significant changes in the regulatory mechanisms which govern producers, handlers, and their certifying agents in determining the materials, practices, and procedures used in an organic operation.

One regulatory mechanism used in the first proposal was an ''order of preference'' scheme for selecting organic practices or materials employed in production and handling. This scheme was proposed for a number of areas: Crop rotation; manuring practices; soil fertility and nutrient management; seeds and planting stock selection; crop pest, weed, and disease prevention and management; livestock health care; selection of handling ingredients; and prevention and facility pest management. There was also a general order of preference requirement that mandated the use of nonsynthetic substances in preference to synthetic substances.

Comments from at least one industry association supported using orders of preference to assure that choices made by producers and handlers will be as consistent as possible with organic farming and handling principles. Others, including several organic certifying agents, felt that the conditions for choosing a lower order of preference were not specified clearly enough and could result in inconsistent enforcement of the standards. Some commenters thought that certifying agents would be overly burdened by having to review and approve the justification in the organic plan for choosing less preferable practices, although some stated that if the criteria for choosing a lower order of preference were clarified and documentation of the reasoning behind the choice was explicitly required, then this scheme would be workable. Some noted that ranking practices and inputs according to their suitability is analogous to the ''approved, restricted, prohibited'' scheme which many State and private certification programs employ. A few commenters expressed the belief that establishing provisions to issue variances would address their concerns and provide for adequate oversight and enforcement concerning practices, procedures, and inputs that are considered to be acceptable but less desirable for organic production and handling.

However, several commenters, including consumers and organic certifying agents, asserted that ''preference'' could be interpreted as purely based on the personal choice or convenience of the producer or handler. Some certifying agents indicated that the soil fertility order of preference was too complex and difficult to enforce. A number of consumers disliked this concept because it permitted some deviation from the most desirable standards, such as use of organically produced seeds. Another commenter speculated that this scheme could be interpreted as establishing different levels of ''organicness.'' Although these interpretations do not reflect the intent of the first proposal, in the interest of clarity, we have removed references to orders of preference in the current regulatory text. We also removed the general requirement for orders of preference and to simplify the scheme so that it will be less burdensome for certifying agents to enforce. Several provisions in this proposal, including the seeds and planting stock practice standard (§ 205.204) and the crop pest, weed, and disease management practice standard (§ 205.206) will allow less desirable practices or substances to be used only if the preferred alternative is either ineffective or not commercially available. As was true of the first proposal, justification for choosing a less desirable alternative, such as nonorganic seeds or planting stock, must be documented in the relevant organic system plan and approved by the certifying agent.

Several commenters, including industry and environmental associations, also took issue with the use in the first proposal of performance standards, which specify the required outcome but not the practices that must be used to achieve it. The general provision that any practice or substance used in an organic operation not contribute to measurable degradation of soil or water quality is an example of such a performance standard. Objections to the use of performance standards referred to the nature of organic production standards, which focus on the production process and not quantifiable outcomes such as pesticide residue levels. Some of these commenters asserted that such a mechanism would relegate organic standards to a risk assessment model, which is not appropriate for evaluating a system of organic management.

We agree that standards for an organic management system cannot be reduced to measurable outcomes, and this was not the intent of the proposed performance standards in the first proposal. The evaluation of measurable indicators as benchmarks of the proper functioning of a management system is compatible with the overall requirement that practices be implemented that are consistent with a system of organic farming and handling. Such indicators help to determine whether a given operation is in compliance with the regulations. For example, the crop rotation provisions in this proposal list a series of functions, including weed management, that should be provided by an appropriate rotation. While the possible types of rotation that could achieve this objective are virtually limitless and could not be specifically prescribed, recording changes in weed populations could document the

effectiveness of the rotation being implemented.

Another type of regulatory provision employed in the first proposal permitted the use of certain practices or substances only ''if necessary.'' This was proposed for the introduction of nonorganic animals into an organic operation, for using up to 20 percent nonorganic livestock feed, for permitting restrictions on access by livestock to space for movement and access to outdoors, and for use of synthetic processing aids in producing an organic processed product. A producer or handler was required to establish his or her need to use a particular practice or substance based on site-specific circumstances. The basis for each such decision was to be stated in the organic system plan and evaluated by the certifying agent. Many commenters indicated that this provision was not appropriate because, for example, the allowance for the use of 20 percent nonorganic livestock feed, ''if necessary,'' left a loophole that could permit an unscrupulous producer to use nonorganic feed without a valid reason that was consistent with the regulations. We concur that this allowance for practices ''if necessary'' is overly vague and have removed the provision from this proposal. It has been replaced by more specific regulatory restrictions, referred to as practice standards, which better reflect the recommendations of the NOSB.

We have addressed comments that requested more specific guidelines for acceptable organic practices by introducing the concept of practice standards. Practice standards are a series of specific guidelines, requirements, and operating procedures for common agricultural practices such as crop rotation, pest management, and crop nutrient management. The NOSB reviewed portions of the current NRCS practice standards for crop rotation, nutrient management, pest management, composting facilities, and cover or green manure crops at its Washington, DC, meeting in June 1999. NRCS practice standards, while not public health standards, contain rigorous, field-tested provisions which provide specific benchmarks for monitoring the performance of many required organic production techniques. A practice standard can also serve as the foundation for an even more detailed program manual.

For example, we are proposing that composted animal and plant waste materials which are used for soil fertility and crop nutrient management must be produced at a facility in compliance with the NRCS practice standard for a Composting Facility (Code 317). This document establishes minimum acceptable requirements for the design, construction, and operation of a composting facility. A copy of this practice standard may be obtained from any NRCS field office. A copy of this practice standard may be viewed at USDA–AMS–TMD–NOP, Room 2510—South Building; 1400 Independence Ave., SW, Washington, DC 20250–0248. The NOP intends to publish additional practice standards for public comment in the **Federal Register**. We are also holding discussions with NRCS to determine whether farming operations which comply with the certification requirements of the NOP will have the added benefit of being able to participate simultaneously with NRCS cost-share programs.

Incorporating NRCS practice standards into the requirements for organic certification introduces a significantly greater degree of specificity than most organic standards have previously contained. For example, the Composting Facility practice standard includes specifications for facility size, moisture content of the compost pile, carbon-nitrogen ratio, and the interval which certain temperatures must be sustained to achieve a finished product. The practice standard also contains restrictions on source materials which may make it difficult to utilize certain categories of materials which have traditionally been allowed in organic compost production. Enforcing these additional requirements will require far greater oversight from the certifying agent, and expertise in this area will become another factor in accreditation. NRCS uses its practice standards for voluntary cost-share programs, and organic producers may find the requirements burdensome as an added, mandatory expense. Despite the many comments we received criticizing the provisions for performance standards in the first proposal, organic certification schemes have traditionally prescribed outcomes and allowed producers and handlers flexibility in selecting practices used to achieve them. However, we received many other comments stating that more rigorous, clearly defined regulatory mechanisms were needed to protect the integrity of organic certification. We have considered the use of NRCS practice standards to provide clear, consistent, and verifiable guidelines for conducting essential organic production practices. We are particularly interested in receiving specific comment on the feasibility of using NRCS practice standards for compost production and how such practice standards may generally be used to establish organic standards.

(5) *Temporary Variances.* Section 205.201(b) of this proposal provides procedures for establishing a temporary variance from certain requirements of subpart C. The temporary variance is a mechanism for providing regulatory flexibility that did not appear in the first proposal. This mechanism is proposed in response to comments from an industry association and several certifying agents who expressed the need, in certain circumstances, to use practices that would otherwise not comply with the applicable practice standard. Similar mechanisms are used by most existing certifying agents to make exceptions in cases of compelling need, when there is minimal concern for compromising the integrity of an organic system. Temporary variances are established from specific requirements and not, unless specified, from all production standards. They are established for a determined period of time, subject to extension as deemed necessary by the Administrator. For example, the Administrator could, under appropriate circumstances, waive the requirement that a producer must provide livestock with a ration composed of 100 percent organically produced feed.

Temporary variances are created under very specific circumstances and are subject to strong oversight by the Department to prevent potential abuse. This proposal contains three situations in which the Administrator could establish a temporary variance. These situations are: natural disasters as declared by the Secretary in a specific geographical area; business interruption caused by wind, flood, fire, or other catastrophic event; or for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling. In the case of natural disaster declared by the Secretary, the Administrator will establish a temporary variance available to all organic operations within the area designated as affected. For local catastrophic events in which the Secretary does not declare a disaster, the certifying agent is responsible for making recommendations to the Administrator for establishing temporary variances. Catastrophic events must be of a sufficient magnitude and have a direct, immediate impact such that the operation could not continue to function without the temporary variance. Certifying agents are responsible for making a recommendation for a temporary variance in situations prompted by

research needs. Producers and handlers cannot appeal directly to the Administrator for a temporary variance but must make such a request through their certifying agent.

Temporary variances, as proposed here, will not extend to any practice or substance that is expressly prohibited by any provision of the OFPA, the applicable standards, these regulations, or any other Federal, State, or local laws or regulations. For example, a variance cannot be granted for use of an organism produced through excluded methods, for use of sewage sludge as a fertilizer, or for use of irradiation to process an organic product or ingredient. We expect to provide additional guidelines in a program manual to assist certifying agents in evaluating how much of an allowance is appropriate, such as how much of the ration for which animals could come from nonorganic sources under a variance.

Production and Handling (General)—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Definition of ''System of Organic Farming and Handling''.* The first proposal contained a definition of a ''system of organic farming and handling'' to provide an explicit reference point for determining which practices and substances were consistent with such a system. Several industry associations and certifying agents commented that the definition was helpful but lacking in key concepts, such as ''ecological balance,'' ''agroecosystem health,'' and ''biological diversity.'' Several thought the definition should receive greater emphasis in the regulations as a reference point for the underlying principles of organic production and handling and that the NOSB's definition should be used. Although we considered many of the concepts discussed by commenters, only the scope and not the meaning of the original definition has been changed. The definition in this proposal is based on the one we developed in consultation with the NOSB but is limited to concepts that are incorporated into the OFPA. Measuring compliance with the component-based mandates of the OFPA, such as fostering soil fertility and preventing water contamination by manure, does not require criteria as far-reaching as ''agroecosystem health'' or ''biological diversity.'' We also took into consideration the costs to comply with such open-ended requirements and determined that this could be excessively burdensome. Synergistic benefits may be associated with organic production and handling systems, but the OFPA requires only that individual components of the system—soil, water, wild crop environment—be protected. Adherence to the conservation practices found in the individual practice standards will result in cumulative benefits to the agroecosystem, but producers and handlers would have difficulty measuring compliance at this scale. Establishing standards that address individual components of an organic farming system, such as tillage practices and manure management, will directly and beneficially impact the entire ecosystem. For the purpose of enforcement, however, we propose retaining the component-based criteria for evaluating a system of organic farming and handling.

(2) *Commercial Availability Standard.* The first proposal allowed certain materials and practices, such as nonorganic seeds and nonorganic minor ingredients in a product labeled organic, to be chosen if preferable alternatives were not ''commercially available.'' We have retained the commercial availability principle in this proposal but have limited its use to the provisions addressing the selection of organic or untreated seeds and planting stock. A number of producers, consumers, and certifying agents expressed concern that producers or handlers not be permitted to base claims of commercial unavailability on any price difference between organic and nonorganic inputs. They argued that the term, ''feasibly and economically,'' in the proposed definition of ''commercially available'' were too vague to be enforceable. Comments from an industry association supported the use of this concept but requested a more specific definition that could be used to assess the economic dimension of commercial availability. The NOSB has also cited commercial availability as a valid criterion for allowing some flexibility in the choice of inputs and stated that the term is applicable to the quantity and quality of available product as well as its cost.

Although commercial availability is not defined in the OFPA, the concept is well established within current certification programs and the commercial world in general. To be considered commercially available, a preferred input must be known and readily available in the sense that a producer or handler can locate and acquire the quantity and quality of product needed to sustain his or her operation. The producer or handler must make a good faith effort to procure the preferred input but should not be expected to rely on an inconsistent supply of a necessary commodity. We do not provide a formula for determining when price difference alone is enough to justify purchase of the less desirable input because of the multiple factors which could affect such a decision.

By limiting the application of the commercial availability standard to the selection of organic or untreated seeds and planting stock, we are limiting its use to relatively narrow and well defined markets. A producer must justify a choice based on commercial availability when submitting an organic plan to the certifying agent, and it must be supported by evidence of a good-faith effort to obtain the preferred input. The attempt to source an input from known suppliers and an investigation to discover potential new suppliers constitute the producer's good-faith effort. Certifying agent approval of the organic plan provides sufficient protection against abuse of this provision. Although comments reflected concern that too many allowances for nonorganic inputs could dilute the integrity of certification, the organic industry has built its reputation while using the commercial availability exemption for sourcing certain materials. Certifying agent oversight can ensure that it works in the NOP as well.

Production and Handling (General)—Additional Provisions

Upon further review of the provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *Dual Use of an Organic System Plan.* Section 205.201(b) allows a producer or handler to submit an organic production system plan developed to meet the requirements of another Federal, State, or local regulatory program if the plan fulfills the applicable requirements of this section. Government agencies may have programs in place that require participating agricultural producers or handlers to develop and follow a management plan. For example, the NRCS Environmental Quality Incentives Program (EQIP) requires a conservation plan. An organic production system plan could be incorporated into such a conservation plan and fully comply with the requirements proposed in § 205.201 of this proposal. This new provision could reduce the paperwork burden for an operation that participates in more than one program requiring a farm conservation plan.

Crop Production—Changes Based on Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Biosolids.* The first proposal requested public comment on the possible use of biosolids as a means of enhancing soil fertility on an organic agricultural operation. Our interpretation of the term, ''biosolids,'' is synonymous with the definition of sewage sludge contained in 40 CFR part 503. In response to the comments we received, this proposal adds biosolids to the list in § 205.203(e)(2) of substances that are specifically prohibited for use in organic production.

The first proposal reviewed some historical information about the Federal enforcement of biosolids use and the steps taken by EPA, FDA, and the U.S. Department of Agriculture (USDA) to ensure that biosolids are safe to use on crops for human consumption. Comments were solicited as to whether biosolids should be permitted or prohibited in organic production. The first proposal noted that the NOSB recommended that biosolids should be classified as synthetic and were not appropriate for use in organic crop production. The NOSB took this position at its 1996 meeting in Indianapolis, IN, and reaffirmed it at its 1998 meeting in Ontario, CA.

We received hundreds of thousands of comments, virtually all of which strongly opposed the use of biosolids in organic agriculture. The vast majority of the commenters stated that biosolids can contain synthetic substances prohibited in organic agriculture, such as industrial waste, street runoff containing petroleum products, and household waste contaminated with cleaning products, polychlorinated biphenyls (PCB's) and dioxins. Commenters indicated that sewage sludge should not be allowable because it may contain synthetic materials prohibited in organic production which are not restricted under EPA regulations. Many commenters stated that biosolids are not currently allowed in organic production and that permitting their use would run contrary to consumer expectations. Such an allowance would place producers at a competitive disadvantage in domestic and international markets. While sewage sludge may be safely used in conventional agriculture, allowing its use under these standards would be inconsistent with the historical understanding of organic fertility management shared by producers and consumers. Therefore, this proposal prohibits the use of sewage sludge in organic production.

(2) *Tillage and Conservation Practices.* While no comments objected to the inclusion of tillage and cultivation practices in the first proposal, a few took issue with the requirement that these practices result in ''no measurable degradation'' of soil quality. In this proposal, the concept of '' no measurable degradation'' has been replaced with the requirement to ''maintain or improve'' soil quality. We agree with commenters who suggest that prevention of soil erosion is an important consideration for the selection of tillage and cultivation methods and have included a requirement that tillage and cultivation practices maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion. We have removed other references to preventing measurable degradation when using plant or animal wastes in the first proposal and replaced them with a requirement, in § 205.203(c), that the producer manage these materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. In accordance with several comments received, this provision frames the requirement in terms of achieving a positive outcome rather than avoiding a negative one. This proposal specifies the types of measurable degradation that could result from improper or excessive application of plant or animal waste materials, and producers, in consultation with the certifying agent, will identify potential problems and address them in the organic system plan. The organic system plan must also identify appropriate monitoring activities to ensure that the ''maintain or improve'' requirement is being met. For example, a producer who manages an on-farm composting facility might make regular observations of the pile to check for leaking and periodically sample a nearby stream for nitrate content.

(3) *Application of Raw Manure.* The first proposal requested public comment on appropriate guidelines to ensure that use of raw animal manure would not cause contamination of food products by pathogens that cause foodborne illness. The OFPA restricts the use of raw manure by requiring that a reasonable period of time elapse between its application to a crop intended for human consumption and the harvest of that crop. This period of time must be approved by the certifying agent, but in no event may it be less than 60 days. The OFPA stipulates that the certifying agent determine the interval between the last application of raw manure and harvest of the crop to ensure the safety of the crop. Furthermore, the OFPA prohibits raw manure from being applied to any crop in a way that significantly contributes to water contamination by nitrates or bacteria. The first proposal contained an order of preference which favored the use of composted materials, including manure, as inputs for soil fertility but allowed raw manure applications subject to the 60-day minimum preharvest interval contained in the OFPA.

Many public comments addressed the issue of raw manure use, and some industry, producer, consumer, and environmental groups submitted substantial technical information. Many of these commenters addressed the human health risk associated with the use of manure in organic crop production. Most of these comments suggested that a determination of sufficient time to ensure the safety of a crop depends on soil and climate conditions, but that the 60-day period specified in the OFPA was not sufficient. Some commenters cited various amounts of time that might be considered safe. Other commenters stated that no interval between application and harvest could be considered safe and recommended prohibiting the application of raw manure to any crop. The NOSB had extensive deliberations on the use of raw manure in organic crop production at its June 1999 meeting in Washington, DC.

The OFPA's requirement that raw manure be applied in a manner that ensures the safety of the crop presents a unique regulatory challenge. We have consistently maintained that the NOP is for marketing, not food safety, purposes. Organic production and handling standards, which are not based on risk assessment of public health consequences, may differ from the requirements established by agencies that are responsible for food safety regulations. The OFPA's requirement that the application of raw manure ensures the safety of the food to which it has been applied requires the NOP to move toward establishing a public health standard. This requirement is especially challenging given that there is no Federal oversight of the application of raw manure to any kind of crop nor any public health standards to establish what constitutes safe use of raw manure. Applications of raw manure are a hazardous, threatening

pathogenic contamination of food products, notwithstanding the use of composted manure, which can carry similar hazards.

We have responded to the concerns regarding the application of raw manure to organically produced crops by proposing the standards contained in § 205.203(c)(1). We propose that raw animal manure must be composted, unless it is applied to land used for a crop not intended for human consumption, incorporated into the soil not less than 120 days prior to the harvest of a product in direct contact with the soil surface or particles, or incorporated into the soil not less than 90 days prior to the harvest of a product the edible portion of which does not have contact with the soil surface or particles. However, many site-specific variables affect the viability of pathogens in raw manure, and we cannot determine whether this standard will be sufficient under all conditions to fulfill the safe food requirement contained in the OFPA. We are requesting comment on the development of more comprehensive standards that certifying agents are capable of enforcing. We are also requesting comment on how to regulate the authority to determine the ''reasonable period of time'' between the last application of raw manure and harvest of a crop which the OFPA delegates to the certifying agent. Given the need for far greater scientific understanding of the spread of pathogens in raw manure, we do not consider that certifying agents should be expected to make the determination of safety.

Several comments were received which suggest that any use of raw animal manure could jeopardize human health and that the use of raw animal manure by organic farmers thereby increases the risk that organic foods may not be as safe as conventionally produced foods. We recognize that our knowledge of the risks from foodborne pathogens has advanced since the OFPA was passed a decade ago, and that safety precautions have been strengthened accordingly. Therefore, we are seeking further guidance for developing regulations that minimize the potential for contamination of crops grown for human consumption by pathogens from raw animal manure. This approach is consistent with the traditional organic certification procedures which have restricted the use of raw manure for environmental as well as health concerns. Other Federal and State regulatory programs may impose additional requirements on the use of raw manure in crop production which could be applicable to organic operations.

The first proposal required that management practices for the application and storage of raw manure be implemented in a manner that does not significantly contribute to contamination of water by nitrates and bacteria, including human pathogens. The use of the word, ''significantly,'' in this provision is a direct reference to the authorizing language in the OFPA (Section 2114(b)(2) (C)). However, commenters suggested that this language implies that ''insignificant'' contamination would be acceptable. This proposal requires that soil management practices aim at preventing, to the extent possible, any contamination of water by nitrates and pathogenic bacteria.

(4) *Use of Treated Seed.* The first proposal permitted the use of treated seeds if the same variety was not commercially available in untreated form or if unanticipated or emergency circumstances made it infeasible to obtain untreated seeds. In this context, ''treated seed'' refers to the application of a pesticide to a seed prior to planting and does not include the use of a disinfection treatment for a seed that is intended for sprouting and food use. A number of comments from producer and industry groups suggested that this was appropriate but that a producer should have to choose an ''equivalent'' untreated seed variety that was commercially available. The term, ''equivalent,'' indicates that two seed varieties have similar performance attributes, such as resistance to drought and insects, and production traits, including yield, size, and shape of the commodity. We agree with this provision because it favors a nonsynthetic input over a synthetic one and have, therefore, included it in this proposal. We are also requiring that, when selecting a nonorganically produced seed, a producer select an untreated equivalent variety in preference to one which has been treated with an allowed synthetic treatment.

Some comments objected to any allowance for the use of treated seeds or planting stock, citing the prohibition in 2109(c)(3) of the OFPA (7 U.S.C. 6508(c)(3)) on the use of transplants that are treated with any synthetic or prohibited material. We recognize that the use of synthetic seed treatments, some of which are acutely toxic, may seem inconsistent with a system of organic production and handling, but it is an established practice in State and private certification programs and is supported by provisions of the OFPA. We believe that retention of the commercial availability requirement, a preference for untreated, nonorganically produced seed over treated, nonorganically produced seed, and the use of temporary variances in this proposal provide an appropriate context for regulating the use of synthetic seed treatments.

The requirement from the first proposal that all seeds, annual seedlings, and planting stock be organically produced is retained in this proposal. Similarly, this proposal contains a comparable exception to the requirement so that nonorganically produced seeds and planting stock could be used to produce an organic crop when an equivalent organically produced variety is not commercially available. A producer's decision to use nonorganically produced seeds and planting stock for reasons of commercial nonavailability of equivalent organic varieties must be included in his or her organic plan and agreed to by the certifying agent. We decided to retain these provisions from the first proposal after receiving comments from producer and industry groups that acknowledged that the supplies of organic farm inputs will not be sufficient to provide for the seed and planting stock needs of all organic operations in the near future. We have added the requirement that producers select equivalent untreated seed over treated seed when commercial availability allows them to use a nonorganically produced variety. We recognize that these provisions could lead to certifying agents facing numerous decisions regarding commercial availability and equivalency in the organic system plans they review. This degree of oversight is warranted, however, to ensure that the use of synthetic materials in organic production is kept to a minimum. We are not extending the commercial availability exception to the requirement for organically produced annual seedlings because the comments indicated that the organic input suppliers are effectively meeting this demand.

In contrast to the first proposal, we propose that any synthetic seed treatment used in organic production must be included on the National List of synthetic substances allowed for use in organic production. We base this requirement on the OFPA, which identifies ''treated seed'' as a category of synthetic substances eligible for inclusion on the National List. We believe that including specific seed treatments on the National List will satisfy the requirement in the OFPA that a farmer shall not apply a material to or

engage in a practice on seeds or seedlings that is contrary to or inconsistent with the applicable certification program. The approach we are proposing is also consistent with current practice in the organic industry. The NOSB endorsed this approach at its 1994 meeting in Santa Fe, NM, by recommending that seed treated with synthetic fungicides appearing on the National List be allowed when nontreated varieties are commercially unavailable.

We propose that producers or handlers may request a temporary variance due to unavoidable natural disaster in order to use nonorganically produced annual seedlings. The temporary variance will be appropriate in instances in which an unexpected event such as a frost, flooding, fire, or other catastrophic event destroyed the producer's nontreated planting materials and no organically produced replacements are commercially available. This provision cannot be used to compensate for mismanagement by the producer. For example, a producer who planted seedlings prior to the recognized frost date and lost his or her crop to a freeze could not claim that this disaster was unavoidable. This provision requires that the producer make all reasonable efforts to protect his or her seeds, annual seedlings, and planting stock before being allowed to substitute with treated replacements.

Some commenters cited the prohibition in section 2109(c)(3) of the OFPA against using transplants that are treated with any synthetic or prohibited material as justification for prohibiting the use of synthetic seed treatments. However, the statute permits the use of seeds and seedlings treated with substances included on the National List of allowed synthetic substances. The seemingly inconsistent requirements for seedlings and transplants, functionally equivalent terms, have made this a difficult issue to resolve. The first proposal attempted to reconcile these differences by defining transplant as an annual seedling produced on an organic farm and transplanted to a field on the same farm operation to raise an organically produced crop. Many commenters felt that distinguishing between annual seedlings which originated on and off the operation was not a valid approach. We concur, and have removed this definition, and interpret the term,'' transplant,'' as applying to any seedling which is transported and replanted, regardless of whether it originated on the operation or not. We interpret the prohibition on using a transplant treated with any synthetic or prohibited material as taking effect after the seedling has been physically transplanted. Therefore, the prohibition only applies to materials applied after transplanting and not to the synthetic treatment included on the National List, which may have been applied to the seed that produced the seedling.

The application of disinfectants to seeds used for sprouting represents a unique dimension of the seed treatment issue. Raw sprouts pose a potential food safety risk because the conditions under which they are produced—growing time, temperature, water activity, pH and nutrient content—can foster the rapid growth of bacteria. In 1999, FDA issued guidance advising sprout producers and seed suppliers of measures to reduce microbial hazards common to sprout production. These measures include treating seeds with one or more approved methods such as presprout soaking with 20,000 ppm calcium hypochlorite. Based on the recommendation of the NOSB, the Secretary has included on the National List in this proposal three chlorine materials to disinfect and sanitize food contact surfaces. However, these materials carry the annotation that residual chlorine levels in water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, which is well below the 20,000 ppm level that FDA currently advises sprout producers to follow.

Existing State and private certification programs have diverged in their response to the FDA guidance on chlorine treatments. While treating food products with high concentrations of chlorine has traditionally been prohibited, some certifying agents currently allow sprout treatment at the 20,000 ppm level. Producers of organic sprouts are finding it increasingly difficult to balance the FDA guidance, the expectations of consumers, and the requirements of their certifying agents. This proposal contains no specific guidance on the use of chlorine treatments on seeds used in sprout production. As synthetic compounds, chlorine materials would have to be added to the National List at specified concentrations to be used for disinfecting sprouts. Without a specific National List exemption, operations that treat sprouts at the level established in the FDA guidance could not be organically managed.

(5) *Crop Rotation*. The OFPA requires an organic crop production plan to foster soil fertility through practices that include a crop rotation. The first proposal required the establishment of a crop rotation or other ''means'' of ensuring soil fertility and effective pest management but did not provide explicit restrictions concerning situations in which those means could be substituted. Producers and producer groups sent many comments stressing the importance of a proper crop rotation for successful organic crop production and objecting to the vague allowance for other methods to be used in its place. Although we have not changed the definition of crop rotation from the first proposal, the new practice standard eliminates the possibility that an organic producer will substitute some other practice for a crop rotation. This proposal does, however, allow for variances from an approved crop rotation plan due to natural disasters, including weather.

A few commenters made the point that, although the OFPA includes a provision for a crop rotation as a means of improving soil fertility, a crop rotation serves other critical functions as well. We reviewed the NRCS practice standard for crop rotation (Code 328) which addresses many of the concerns raised in public comment. Accordingly, § 205.205 of this proposal requires the producer to implement a crop rotation, including, but not limited to, cover crops, sod, green manure crops, alley crops, and catch crops. These techniques serve the following functions as applicable to the operation: maintain or improve soil organic matter content; provide for effective pest management in annual and perennial crops; manage deficient or excess plant nutrients; provide erosion control to minimize soil loss; and manage subsurface water to prevent transport of dissolved materials.

A few comments suggested requiring that rotation plans include sod or legumes, which serve to improve soil organic matter content and increase soil nitrogen supplies to meet the demands of a following crop. However, all of these functions could be fulfilled through many different types of rotation plans, which could only be developed according to the site-specific climate, soil type, and type of crops or livestock produced on a given operation. In the interest of flexibility, therefore, this proposal does not specify what crops have to be included in a crop rotation. An organic plan that meets the criteria specified in this proposal must be developed by a producer and approved by the certifying agent.

Proposed § 205.205(b) specifically applies to perennial crops. Under this provision, an orchard plan might include establishment of hedgerow areas that provide habitat for beneficial insects to assist in effective pest management. This provision was added

in response to comments stating that an organic farm plan should address the functions provided by crop rotations even in the case of perennial crops such as orchards and sod. We expect to develop program manuals containing more detailed information on different types of rotations, including methods to fulfill the prescribed functions for perennial crops, that are suitable to a wide range of types of operations and geographic conditions.

(6) *Prohibition on Cytotoxic Pest Control Substances.* In response to several comments, we have deleted the provision in the first proposal to prohibit use of a synthetic carbon-based substance having a cytotoxic mode of action for any use as a pest control substance. Some commenters interpreted this provision to mean that this single criterion would substitute for those specified in the OFPA for evaluating substances proposed for inclusion on the National List. Other commenters, including industry groups, objected to this provision because it has not previously been part of certification standards and its meaning was too ambiguous. Some substances that have historically been accepted for organic production could have cytotoxic effects when used in inappropriate concentrations. Although this provision added to and did not replace the evaluation criteria contained in the OFPA and eliminated the need for the NOSB to review clearly inappropriate substances, it has been removed from this proposal in the interest of clarity.

Crop Production—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Buffer Zones.* Section 205.202(a)(3) of this proposal requires that any land on which organic crops are produced have distinct, defined boundaries and buffer zones, such as runoff diversions, to prevent the unintended exposure of the crop to prohibited substances from adjoining land. Several commenters suggested that the regulations should specify a minimum size for buffer zones, as is currently required by some organic certifying agents. Although specifying a size for these zones would establish a more definable requirement, it could also impose unnecessary burdens on some organic producers without offering greater protection of organic fields and crops from unintended contact with prohibited substances. Another commenter argued that buffer zones should not be required for unmanaged lands such as wilderness areas or abandoned farms. There might be no need for a buffer zone if an organic farm were completely surrounded by wilderness or abandoned farms, which is one reason why a the size of a buffer zone should not be specified. This proposal leaves the determination of an adequate buffer zone to the organic producer and the certifying agent on a case-by-case basis. Buffer zone provisions are an important part of each organic production system plan, and we will provide guidelines for buffer zones in program manuals.

(2) *Nonorganic Plant and Animal Waste Materials.* The first proposal permitted the use of any uncomposted plant or animal wastes. It also allowed use of composted plant or animal wastes obtained from nonorganic sources, such as commercial compost products. Several consumer and environmental groups objected to permitting the use of plant or animal wastes from nonorganic sources. Such materials, they argued, could potentially contain residues of prohibited substances that could compromise the integrity of the organic farm system. However, off-farm plant and animal wastes from food processing, municipal yard waste facilities, and other sources are used extensively in existing organic operations and are generally permitted by organic certification programs. Bone meal, fish meal, and seaweed meal are also commonly used as organic farm inputs. Commercial fertilizer products that contain mixtures of such plant and animal by-products are commonly permitted for use in existing organic certification programs, subject to certifying agent review. Using such organic wastes is consistent with a system of organic production and handling, which calls for recycling organic wastes to return nutrients to the land. We believe that concerns about potential contaminants in plant and animal waste materials can be addressed by the requirement in this proposal that these materials be managed in a manner that prevents such contamination. For example, cotton gin trash that had been treated with a prohibited substance could only be used if the organic system plan specified composting the material before adding it to the soil. Composting has been shown to effectively biodegrade synthetic organic compounds, and the organic system plan could also call for the compost or soil to be monitored regularly for specific residues.

Finally, the first proposal and this proposal prohibit the use of any commercially blended fertilizer product that contains a prohibited substance, as required by the OFPA. Although a number of commenters worried that a product containing toxic synthetic substances as inert ingredients could be used for organic production, this prohibition prevents such products from being used. For this reason, the use of any composted or uncomposted plant or animal wastes to supply soil or crop nutrient is permitted without further limitation other than preventing contamination of soil or water by pathogenic organisms, heavy metals, or residues of prohibited substances. The certifying agent will be expected to have the expertise to recognize materials that might be of concern and ensure that they are properly addressed in the organic system plan. We expect to provide additional guidelines in program manuals to help evaluate whether animal manure is fully decomposed, as well as guidelines for other types of materials to address potential soil or water quality concerns. We acknowledge the need to examine carefully commercial blended fertilizers and soil amendments to ensure that such products do not contain prohibited substances.

(3) *Chemically Altered Plant or Animal Waste Materials.* The first proposal allowed the use of a composted or uncomposted plant or animal waste material that had been chemically altered by a manufacturing process—such as leather meal, newspaper, and biosolids—if the material was included on the National List of allowed synthetics. Only newspaper was proposed for inclusion on the National List. A few commenters objected to this allowance, although newspaper is commonly permitted as a mulch material or as an ingredient in compost in existing organic certification programs and was recommended for this use by the NOSB. The National List review process offers an adequate safeguard to ensure that other waste materials that may be permitted in the future will be consistent with a system of organic production and handling, and we propose to retain this provision in § 205.203(c)(5) of this proposal.

(4) *Soil and Crop Mineral Nutrients.* This proposal includes provisions for supplying soil and crop mineral nutrients that are similar to those in the first proposal. While use of a proper crop rotation and recycled plant and animal wastes can often provide all the mineral nutrients required by crops, supplemental sources of these nutrients are sometimes needed. Section 205.203(d) of this proposal permits a producer to supply soil and crop nutrients through use of mined minerals and other nonsynthetic sources. Synthetic micronutrients are also allowed if they are included on the

National List. Ash from plant or animal materials can be used, as long as the burned material was not treated or combined with a prohibited substance and was not included on the National List of prohibited nonsynthetic substances. For example, ashes from treated wood or incinerator ash are not permitted, nor is ash from manure, which is on the National List of prohibited nonsynthetics. The prohibition of burning crop residues on the farm in the first proposal has been retained, but an exception for burning trimmings of perennial crops to control diseases has been added in response to an NOSB recommendation.

Commenters raised no objection to the proposed allowance for mineral substances of low solubility, including lime, greensand (glauconite), and rock phosphate, which have traditionally been permitted in organic certification programs. However, numerous producers and certifying agents expressed concern about the allowance for use of mined mineral substances of high solubility or salinity. These include substances such as sodium (Chilean) nitrate or potassium nitrate (niter), potassium chloride (muriate of potash), langbeinite (sulfate of potash magnesia), and potassium sulfate. Because of their potential to degrade soil quality by contributing to soil salinization, these substances, along with the synthetic micronutrients that are on the National List of allowed synthetics, were allowed only when used in cases of known nutrient deficiency. Many commenters objected to the use of sodium nitrate and potassium nitrate in organic production, and some contested the determination that nonsynthetic, mined sources of potassium nitrate are available. Some also objected to allowing potassium chloride, which has traditionally been prohibited in most organic certification programs. Several commenters argued that no highly soluble source of nitrogen, synthetic or not, should be permitted for application to soil in an organic management system. They indicated that these materials are not permitted in international organic standards, and approval could potentially harm exports of organic products. The NOSB reviewed Chilean nitrate in 1995 and recommended certain restrictions on the use of this material, which is allowed with restrictions in some existing organic certification programs and prohibited in others. In accordance with the NOSB's recommendation, this proposal permits these materials to be used according to justifications in the organic system plan. More detailed guidance will be provided in program manuals on the appropriate justifications for the use of highly soluble nutrient sources, including plans for discontinuing their use. Soil or tissue testing will be an important aspect of justifying the need for any such supplementation. Producers concerned about requirements for export markets can request certification to the standards required by individual contracts.

(5) *Nonorganically Produced Planting Stock.* The first proposal allowed nonorganically produced planting stock used to produce a perennial crop to be sold, labeled, or represented as organically produced after the planting stock had been managed on an organic operation for a period of no less than 1 crop year. This provision is authorized by section 2107(a)(11) of the OFPA (7 U.S.C. 6506(a)(11)). Some commenters thought this provision provided a loophole for indiscriminate use of treated planting stock on an organic operation. They argued that a producer could purchase treated nursery stock and list it as organic planting stock in the organic plan after only 1 year. However, producer and industry groups supported this provision as an important stimulus to the organic input suppliers, since it allows a nursery operation to purchase planting stock from a nonorganic operation and later resell this stock as organically produced. The first proposal described an organic nursery operation which could purchase nonorganic dwarf apple rootstock and graft it with locally adapted varieties and then sell the resulting planting stock as organically produced after raising it organically for at least 1 year. We agree that the potential benefits of this provision outweigh its possible abuses, and § 205.204(d) of this proposal permits nonorganically produced planting stock to be used as planting stock to produce a perennial crop to be sold, labeled, or represented as organically produced after the planting stock has been under a system of organic management for no less than 1 crop year.

(6) *Pest, Weed, and Disease Control Practice Standard.* The OFPA sets forth practices such as the use of natural poisons that persist in the environment or plastic mulches that are prohibited or restricted in the control of pests, weeds, and diseases in organic crops. It also lists the following categories of active synthetic pest, weed, and disease control substances that may be considered for exemption if they are included on the National List: Copper and sulfur compounds; toxins derived from bacteria; pheromones; soaps; horticultural oils; fish emulsions; treated seed; vitamins and minerals; livestock parasiticides and medications, and production aids, including netting, tree wraps and seals, insect traps, sticky barriers, row covers, and equipment cleansers. Section 205.206 of this proposal contains the practice standard to implement the provisions of the OFPA for synthetic pest control substances.

We have made a minor modification by eliminating one element of the order of preference which commenters considered too difficult to enforce. There is no distinction made in this proposal between pest prevention and control practices in terms of preferability. However, a provision in the first proposal that permitted application of a botanical or allowed synthetic pest control substance only if previously delineated methods were ineffective has been retained. This provision is supported by public comments from producers, certifying agents, and many consumers who emphasized that such substances, while sometimes necessary, should only be permitted as a last resort. This provision requires a producer to document the need for copper and sulfur fungicides, dormant oils, or similar materials in their organic system plan.

(7) *Wild-crop Harvesting.* We received few comments on the provision in the first proposal concerning wild-crop harvesting, and, therefore, this proposal retains similar requirements. Changing the term for the location from which wild crops may be harvested from ''land'' to ''area'' is the only substantive difference between the first proposal and this one. We made this change to be consistent with the language in the OFPA. One commenter stated that maps should be required as part of the certification process. A certifying agent could reasonably require such maps to assist in evaluating the organic system plan, but we have not made their inclusion a requirement.

The provisions of this section apply only to the management of wild crops. The OFPA includes ''fish used for food, wild or domesticated game, or other nonplant life'' in the definition of livestock, and we are considering additional standards for animals and animal products harvested from the wild. We received substantial public comment on the opportunities for developing standards for marine and freshwater aquatic animals (encompassing finfish and shellfish) and apiculture operations. Additional comments addressed the feasibility of developing production standards for harvesting wild terrestrial animals.

The certification of aquatic animals has very limited precedent among existing certifying agents and will require additional dialogue before credible standards can be developed. The FY 2000 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act provides funds for the NOP to convene national meetings to consider the development of organic standards for aquatic animals. Meetings will be held in Alaska, Alabama, and Rhode Island. Simultaneously, the NOP will be working with stakeholders from the aquaculture community to consider standards for the production of farm-raised aquatic animals.

The certification of apiculture operations has some precedent among certifying agents. However, due to many unique production considerations, organic certification for apiculture operations has been very limited. Public comment on the first proposal indicated that consensus on critical apiculture issues including forage area and pest management will require considerable additional dialogue. The NOSB has expressed interest in leading the discussion of the key issues pertinent to certification of apiculture operations. We will incorporate public participation and the NOSB's recommendations into future production standards for apiculture as well as for other wild harvested livestock operations as needed.

(8) *Practice Standards for Specialty Crop Operations.* Several organic certifying agents and producer associations commented that the proposed rule did not sufficiently detail prescribed practices for many specialized aspects of organic production and handling, such as mushrooms, greenhouses, and aquaculture. We concur that such details are lacking, and to a certain extent, this proposal addresses that gap through the introduction of more detailed practice standards. In some cases, more specific regulations appropriate for such specialized operations, including aquaculture, mushroom production, and greenhouse operations, will be filled in as recommendations are developed by the NOSB. Beyond this, the Department expects to address the need for greater specificity through program manuals, which will provide more detailed guidance about site-specific decisions. For example, program manuals could include examples of crop rotation plans suited to different geographic regions, soil conditions, and types of enterprises. Program manuals could also be used to provide guidance about how indicators of the condition of the natural resource base can be qualitatively assessed using simple field observations so that the impact of site-specific practices on soil and water quality can be documented in the organic plan.

Crop Production—Additional Provisions

Upon further review of the provisions in the first proposal, we have decided to propose the following additions and changes.

(1) *Mandatory Phytosanitary Treatment of Seeds, Seedlings, and Planting Stock.* Section 205.204(e) of this proposal contains a new provision that permits the use of treated seeds, seedlings, or planting stock in cases in which Federal or State phytosanitary regulations require treatment. For example, some States require seed potatoes or strawberry crowns to be treated to prevent the spread of plant diseases. The OFPA authorizes reasonable exemptions from specific requirements for compliance with Federal or State emergency pest or disease treatment programs. This provision is also consistent with the NOSB's recommendation on the use of treated planting stock.

(2) *Restriction on the Use of a Synthetic Pest Control Substance.* The first proposal included a provision that any use of biological or botanical pest control substances or synthetic pest control substances approved for use on the National List had to be used in a manner that did not result in measurable degradation of soil or water quality. This provision has been removed, and § 205.207(e) of this proposal includes a new provision that further restricts use of these substances by requiring the producer to implement measures to evaluate and mitigate the effects of repetitive use of the same or similar materials on pest resistance and shifts in pest types. This requirement can be met by reviewing available research on pest resistance to the substance being used and observing changes in pest populations following repeated application of the substance. Public comments pointed out evidence that nonsynthetic biological and botanical pest control substances, if overused, pose concerns for inducing accelerated resistance in pest populations.

Livestock Production—Changes Based on Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Minimum Period of Organic Management—Nonedible Products.* The first proposal established a 90-day minimum period of organic management for animals from which nonedible products, such as wool, were to be harvested. Many consumers and producers said that a 90-day period was too short and that an animal should be under organic management for at least 1 year before a nonedible organic product could be obtained from it. This requirement is consistent with the provision that dairy animals receive a minimum of 1 year of continuous organic management prior to the production of the milk or milk products to be sold, labeled, or represented as organic. Therefore, this proposal has been revised to state that an animal brought into an organic operation must be under continuous organic management for 1 year prior to the harvest of nonedible products that are sold, labeled, or represented as organic.

(2) *Origin of Mammalian Slaughter Stock.* The first proposal allowed mammalian livestock from a nonorganic source for the production of organic meat if the livestock was brought into an organic operation no later than the 15th day of life, if necessary. Public comment was sought as to the specific conditions, such as commercial unavailability of organic livestock or an emergency situation, that should be a prerequisite for allowing mammalian livestock of nonorganic origin to be designated as organic slaughter stock. Thousands of commenters, along with the NOSB, strongly opposed allowing the use of cows, sheep, or other mammals as organic slaughter stock if they were not organic from birth. Most of them also rejected allowing such practices on an ''if necessary'' basis. Accordingly, § 205.236 requires that mammalian slaughter stock be organically raised from birth.

(3) *Standard for Aquatic Animal Production.* While the first proposal contained no standards solely for aquatic animals in an organic operation, it did contain provisions applicable to their production. The first proposal allowed fish and crustaceans, among other livestock types, to be sold, labeled, or represented as organic if such livestock had been brought into an organic operation no later than the earliest commercially available stage of life. Several commenters suggested that the management of aquatic species differs significantly from mammals and poultry and would require separate regulatory provisions. We concur and intend to develop detailed practice standards for specific aquatic species that will be published for comment and finalized prior to the implementation of the NOP. Given the virtual absence of recognized certification programs for

aquatic operations, including aquaculture, there are limited models on which to base national standards. Therefore, we must create opportunities for producers, consumers, certifying agents, and other interested parties to participate in the development of practice standards. We will hold public meetings in Alaska, Alabama, and Rhode Island to receive comment and anticipate that the NOSB will also provide recommendations.

(4) *Apiculture Standard.* The first proposal allowed bees to be brought into an organic operation at any stage of life and required that the predominant portion of their forage be organically produced. Several commenters, including producer and industry groups, pointed out that bees differ significantly from other livestock types and that the first proposal lacked sufficient details to guide honey producers. Many consumers stated that the provisions proposed for bee forage, which required only that a predominant portion of the bees' forage be organic, were too vague and lenient. Recognizing that the provisions in the first proposal for certifying beekeeping operations were inadequate, we removed them entirely from this proposal. We will review the detailed production and handling standards for beekeeping operations that several certifying agents have developed and assess the feasibility of developing a practice standard. The NOSB has agreed to review and recommend an apiculture practice standard for organic honey production and hive care, including the origin of organic bees.

(5) *Organic Feed Requirement.* The first proposal allowed a producer to feed livestock up to 20 percent of the total feed ration in a given year that was not organically produced. Furthermore, in an emergency situation, the first proposal allowed the Administrator to increase the amount of nonorganic feed that could be provided. Thousands of comments were received opposing any allowance for nonorganic livestock feed, and many thought that no conditions justified providing any nonorganic feed to organic animals. Most producer groups, organic certifying agents, and industry groups, however, recognized that eliminating all flexibility in this regard could seriously inhibit growth of the organic livestock industry and reduce the availability organic livestock products. Several existing certification programs allow some use of nonorganic feed in emergencies, in one case specifying that up to 10 percent of the livestock ration may be nonorganic. Commenters made it clear that the commercial availability of certified organic livestock feed has increased enough to eliminate exemptions based on availability, even in regions such as the Northeast where supplies were previously difficult to obtain. The NOSB also recommended providing an allowance for livestock to receive nonorganic feed in emergency situations, with strict requirements for documentation in the organic system plan.

Based on the public comment received and the recommendations of the NOSB, we agree that allowances for providing nonorganic feed to organically managed livestock should be limited to emergencies, such as fire, drought, flood, and other natural disasters. Accordingly, we have removed the provision from the first proposal that a producer may provide up to 20 percent nonorganically raised feed ''as necessary.'' Exemptions for emergency use of nonorganic feed must be authorized by the Administrator through the procedures for establishing a temporary variance. Producers will work with their certifying agents to determine the minimum percentage of nonorganic feed needed to supply the nutritional requirements of the livestock until the 100 percent organic ration can be restored.

(6) *New Dairy Herd exemption.* The first proposal included an exemption to allow an entire, distinct dairy herd—converted to organic management for the first time—to be fed nonorganic feed up to 90 days prior to the production of milk or milk products labeled as organic. A few producer groups supported this allowance for a one-time, whole-herd exemption to make it feasible for existing conventional dairy farmers to convert to organic management without incurring the costs of 100 percent organic feed for 12 months prior to certification. However, in light of the strong opposition to any nonorganic feed allowance by consumers and its inconsistency with NOSB recommendations, we have eliminated this provision.

(7) *Synthetic Feed Additives.* The first proposal prohibited the feeding of substances containing synthetic amino acid additives and synthetic trace elements to stimulate the growth or production of livestock. In § 205.237(c)(2), the term, ''synthetic amino acids,'' is replaced with the term, ''additives,'' which includes nutritional substances other than amino acids. Some commenters stated that the term, ''additives,'' more precisely reflects the intent of the OFPA, which prohibits the use of growth stimulants. The provision in the first proposal to permit use of synthetic amino acid additives to fulfill the normal nutritional needs of livestock is retained in § 205.237(a).

(8) *Prohibition on Antibiotics.* The OFPA prohibits producers from using subtherapeutic doses of antibiotics. While this suggests that treatment with antibiotics at therapeutic levels is allowed, the OFPA does not contain affirmative conditions for their use. In developing provisions in the first proposal for treating livestock with antibiotics, we reviewed the NOSB recommendations, public input received at NOSB meetings, testimony presented at livestock hearings, and existing State and private standards. We found that innovative production practices and consumer expectations had increasingly diminished the use of antibiotics in organic livestock since passage of the OFPA. At its 1994 meeting in Santa Fe, NM, the NOSB recommended prohibiting the use of antibiotics in the production of organic slaughter stock but allowing their use with extended withdrawal intervals for dairy and breeder stock. By its Ontario, CA, meeting in 1998, the NOSB recommended prohibiting all antibiotic use after animals were brought into an organic operation. Other comments we reviewed favored allowing the use of antibiotics because organic livestock might benefit from receiving such treatments. Other commenters requested that organic producers be prohibited from withholding treatment from sick animals for economic reasons.

The first proposal permitted mammals raised as organic slaughter stock to receive antibiotics in the first 21 days of life and other species to be given antibiotics in the first 7 days of life. The rationale for allowing antibiotic use was based on concerns about the vulnerability of newly born or hatched livestock brought into an organic operation from a nonorganic source. The first proposal permitted organic slaughter stock to originate from nonorganic sources if it was brought under organic management at an early stage of life. Allowing the use of animal drugs could be an appropriate safety net for young organic livestock during their first week of organic management. We requested public comment on the use of animal drugs in the production of organic livestock, including organic slaughter stock. We also published an issue paper in October 1998 entitled ''The Use of Antibiotics and Parasiticides in Organic Livestock Production,'' requesting additional public comment on this subject.

We received thousands of comments from consumers, producers, and industry groups objecting to any allowance for antibiotic use in

organically produced livestock. Many of these comments supported a comprehensive prohibition on the use of antibiotics, regardless of the animal's age or the type of products produced from it. Based on these public comments and the availability of alternative production practices, this proposal prohibits selling, labeling, or representing as organic any animal that has been treated with an antibiotic at any dosage.

(9) *Parasiticide Use.* The first proposal permitted livestock in an organic operation to receive parasiticides topically at any time of life, provided that the producer complied with the prohibition against routine use of a synthetic internal parasiticide. We concluded that, while some earlier public comment favored prohibiting the use of internal parasiticides and the NOSB recommended restricting their use, many producers had indicated that parasiticides were essential to their operations. These producers stated that parasites can threaten animal health at any stage of life and that the use of parasiticides is unavoidable in certain regions of the country. Even under highly controlled situations, some parasites endemic to certain regions can be carried by wild birds, water, or feed. Concerns for the overall health of an animal warranted that parasiticides be used as soon as possible after determining the presence of parasites at a level affecting the health of the infected livestock.

In responding to the first proposal, a large number of commenters stated that synthetic parasiticides should be prohibited in organic production, especially for slaughter stock. The NOSB also recommended prohibiting the use of parasiticides in slaughter animals. For other livestock, the Board recommended that, in certain climates, in certain stages of production, and for certain animals, the use of synthetic parasiticides might be necessary. The Board stated that breeding stock, for example, could receive parasiticides up to certain stages of gestation specific to the type of livestock. Such use of synthetic parasiticides would be highly restricted and include a lengthy period of elapsed time before the animal's offspring would be eligible for use in a certified operation. The Board proposed developing practice standards to address specific instances in which parasiticides could be allowed.

This proposal allows the use of synthetic parasiticides included on the National List for use in organic production on breeder and dairy stock provided that preventative practices and veterinary biologics are inadequate to prevent infestation. This proposal prohibits administering synthetic parasiticides to livestock sold for slaughter. These provisions reflect an attempt to balance the conflicting positions taken by consumers and producers in response to the first proposal and the subsequent issue paper on livestock medications. We recognize that the goal of organic production is to use management practices and natural substances to eliminate, when possible, reliance on synthetic materials. However, we do not believe that a comprehensive prohibition on synthetic parasiticides is feasible for all species and for all regions of the country at this time. Additionally, the new requirements for access to the outdoors for organically managed livestock contained in this proposal may exacerbate exposure to parasites for animals in systems which previously used greater degrees of confinement. These provisions are also consistent with the position of the NOSB, which recommended at its October 1999 meeting to allow a synthetic parasiticide for use on organically raised breeder and dairy stock with the same restrictions incorporated in this proposal.

The OFPA prohibits the use of synthetic internal parasiticides on a routine basis. In the first proposal, the word, ''routine,'' was defined as administering an animal drug ''without cause.'' Many commenters objected to that definition, pointing out that producers would not administer a parasiticide unless they perceived a justifiable cause. Commenters fear that this might lead to dependence on parasiticides rather than a management system to reduce the number of parasites. Therefore, this proposal adopts the NOSB-recommended definition for ''routine'' as use of a synthetic parasiticide on a regular, planned, or periodic basis. The prohibition on using synthetic treatments on a routine basis is retained in § 205.238(c)(4).

(10) *Temporary Confinement.* The first proposal provided that, if necessary, animals could be maintained under conditions that restrict the available space for movement or access to outdoors if other living conditions were adequate to maintain the animals' health without the use of permitted animal drugs. This provision considered the effects of climate, geographical location, and physical surroundings on the ability of animals to have access to the outdoors. We explained that a system of organic production is soil based and that animals should be allowed, as appropriate, access to the soil. This understanding was considered in balance with animal health issues, such as the need to keep animals indoors during extended periods of inclement weather. The determination of necessity was to be based on site-specific conditions described by the producer in an organic system plan or updates to an organic plan, which required approval from the certifying agent. We requested public comment as to the conditions under which animals may be maintained to restrict the available space for movement or access to the outdoors. We also released an issue paper in October 1998 entitled ''Livestock Confinement in Organic Production Systems'' to solicit further public participation in preparing this proposal.

Many commenters stated that, while confinement is appropriate under certain conditions, access to the outdoors is a fundamental tenet of organic livestock production. Commenters cited the widespread prohibition on confinement systems, such as raising poultry in battery cages, contained in domestic and international standards. Producers of organic livestock have incorporated access to the outdoors into viable production systems for all major commercial species, and consumers clearly identify these practices as a distinguishing characteristic of organic products. Some commenters stated that production standards containing broad allowances for confinement would weaken their incentive for purchasing organic products. Some producers pointed out that providing animals access to the outdoors can reduce stress and diminish the risk of transmitting disease. The vast majority of commenters strongly indicated that protection of an animal's welfare or the soil and water resources of the operation were the only appropriate conditions for restricting access to the outdoors. Furthermore, many commenters stated that the condition and properties of the outdoor area to which an animal receives access, such as the nutritional content of pasture, must be important considerations in developing livestock production standards.

Section 205.239(b) of this proposal specifies the circumstances under which animals may be temporarily confined. This new requirement proposes temporary confinement during periods of inclement weather; certain stages of production such as when dairy animals are very young; when the animal's health, safety, or well-being are jeopardized; or when there is risk to soil and water quality. The NOSB specified that the stage of an animal's production

is not intended to include the lactation cycle of dairy animals in which only dry cows would be allowed access to the outside and pasture. The NOSB recommended and we propose that when there is a risk to soil or water quality, livestock should be temporarily confined. Practice standards addressing when and how individual species may be temporarily confined will be developed and published in program manuals. We are also incorporating the NOSB recommendation that ruminants receive access to pasture during the periods they are not temporarily confined.

(11) *Physical Alterations.* This proposal contains a requirement in § 205.238(a)(5) that the producer of an organic livestock operation must perform, as needed, physical alterations on livestock to promote the animal's welfare and in a manner that minimizes pain and stress. Physical alterations include castration and other practices, such as wing clipping, intended to modify or affect the animal's behavior in confinement. We received comments on the first proposal which stated that the performance of physical alterations is integral to a system of organic livestock production which must be addressed in the standards. Subsequently, some commenters on the confinement issue paper drew a connection between certain physical alterations, such as debeaking in poultry, and the conditions for space and mobility under which livestock are raised We anticipate that this subject will be a significant consideration when the NOP engages in equivalency discussions under the Codex Alimentarius guidelines.

While many certification programs have production standards for conducting physical alterations on animals, we cannot identify general consensus on which practices should be approved or prohibited. Many production variables, including breed, the number and concentration of animals raised, and the available natural resource base, influence the selection of production practices. Operations which raise the same species of livestock could, due to differences in production practices, require different approaches to whether and how to conduct physical alterations. We do not have sufficient information at this time to propose species-specific guidelines but anticipate working with producers, consumers, and certifying agents to develop a better understanding on which to act. By including the requirement for conducting physical alterations in a manner which promotes an animal's welfare and minimizes pain and stress in this proposal, we are acknowledging two points. One, physical alterations have an appropriate and at times necessary role in livestock production, and, two, consideration for animal welfare and comfort is an integral component of organic livestock production.

In order to use an animal's welfare and comfort as a condition for establishing standards, we are requesting comment on techniques to measure animal stress. Certifying agents will need objective, verifiable methods to determine whether a producer is fulfilling the livestock management conditions established in the organic system plan. Such methods may include physiological or behavioral approaches to measuring stress and may be directed at individual animals or larger groups such as herds or flocks. The many comments addressing the well-being of animals under organic management indicate that this issue is central to the differentiation of organic production standards from nonorganic practices. We need consistent, verifiable enforcement techniques to ensure that organic producers are capable of attaining and documenting such standards.

(12) *Treatment of Sick or Injured Animals.* In this proposal, any animal that is to be sold, labeled, or represented as organic may not be treated with a prohibited animal drug, including antibiotics, synthetic substances that are not allowed, or nonsynthetic substances that are prohibited. Any substance used as an animal drug in organic livestock production must be approved by FDA or registered by EPA and must be administered in compliance with the Federal Food, Drug, and Cosmetic Act. This proposal simultaneously requires that sick or injured animals must be treated with the appropriate animal medicine regardless of whether organic status is lost as a result of doing so. This requirement has been added in response to an NOSB recommendation. Thousands of comments expressed concern that organic livestock would suffer unduly if producers were not required to provide treatment, especially to save the life of a critically ill animal, rather than risk the suffering or death of the animal simply to maintain its organic status. If the treatment required under this proposal includes the use of a prohibited substance, the animal and any product derived from it must be diverted to the nonorganic market.

(13) *Feeding of Animal By-Products.* Although we received thousands of comments supporting a ban on the feeding of any animal by-products to livestock under organic management, a broad prohibition would prevent certain essential practices, such as feeding milk to young mammals. This prohibition is also inappropriate in the case of carnivorous livestock, such as many aquatic species. We believe that the comments we received were not intended to prohibit such practices but were, rather, motivated by concerns for food safety and the humane treatment of animals. This proposal prohibits the feeding of poultry and mammalian slaughter by-products to organically raised poultry or mammals. This change is based on the thousands of comments that expressed strong consumer preference against adding animal by-products into feed for the same species. There was concern that this practice could expose ruminant animals to Bovine Spongiform Encephalopathy (BSE). FDA regulates animal feed additives and uses its authority to address the human health considerations of animal refeeding. FDA continually revises its regulations to ensure the highest level of protection against known and emerging human health risks. The prohibition on feeding poultry and mammalian slaughter by-products to organically raised poultry or mammals contained in this proposal is based solely on the consumer preference expressed in public comment and is not a food safety standard. Future changes that are made to FDA regulations will be reflected in NOP standards.

(14) *Withdrawal Intervals.* The first proposal required that a producer determine that an animal was fully recovered from the condition for which an animal drug was administered before a product obtained from that animal could be sold, labeled, or represented as organic. In compliance with FDA regulations, this could not have been less than the withdrawal time specified on the label of the animal drug administered. We received comments from producer groups that favored extending the withdrawal times specified on animal drug labels. Many private certification programs applied the principle of extended withdrawal periods to the use of antibiotics in dairy and breeder stock before innovations in production led to such substances being prohibited. The NOSB has continued to include extended withdrawal period annotations with its recommendations for the use of parasiticides.

Based on consumer preference and the recommendations of the NOSB, we are proposing an extended withdrawal interval for three animal drugs (Ivermectin, Lidocaine, and Procaine) included on the National List in this proposal. FDA exercises full responsibility for determining and

enforcing the withdrawal intervals for animal drugs. No food safety arguments are used or implied to support the use of extended withdrawal periods. Rather, we determined that extended withdrawal periods are more compatible with consumer expectations of organically raised animals. In emergency situations where the need for a synthetic parasiticide or medicine is unavoidable, an extended withdrawal period would indicate that such use was neither routine nor normal. This approach is consistent with the manner in which organic certification agencies addressed antibiotic use in livestock production. Before the current prohibition on antibiotics became the industry norm, certifying agents allowed their use under restricted conditions, including extended withdrawal intervals, to demonstrate to consumers that such use was genuinely essential.

Livestock Production—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Feed Requirements.* The first proposal required the use of preventive health care practices, including diverse feedstuffs, appropriate housing, well maintained pasture, and good sanitation practices, and this proposal contains similar provisions. It also included provisions for administering appropriate veterinary biologics, vitamins, and minerals, and on selecting species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites. Preventive health care practices were generally supported by comments as being consistent with a system of organic livestock production.

Many commenters requested an explanation of the term, ''diverse feedstuffs,'' and some expressed concern that this provision could permit use of feed supplements which might be prohibited by other Federal, State, or local laws. All provisions proposed in this subpart must be in compliance with applicable laws and regulations, including the Federal Food, Drug, and Cosmetic Act; the OFPA; and our definition of a system of organic production and handling. Vitamins, minerals, and other synthetic or nonagricultural supplements, which appear on the National List of allowed synthetic livestock products in the first proposal are similarly permitted here, and provide a means to diversify an animal's diet. Soybean meal and other organically produced feed concentrates also serve this purpose. We encourage the NOSB to develop and recommend practice standards to provide additional guidance regarding the appropriate variety of feed for specific livestock species. Both the first proposal and this one defer to publications of the National Research Council's Committee on Animal Nutrition to establish nutrient requirements for livestock. Producers and certifying agents will use these publications to ensure that animal nutrient requirements are met.

Handling—Changes Based on Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Irradiation.* In the first proposal, we requested public comment on the compatibility of ionizing radiation (irradiation) with a system of organic production and handling. We also asked if there are effective alternatives to ionizing radiation, such as sanitary practices, heat pasteurization, and incidental additives, that are compatible with a system of organic production and handling, and, if so, how they are compatible. We further asked whether the use of ionizing radiation was considered an essential standard industry practice or good manufacturing practice. Although the NOSB recommended prohibiting the use of ionizing radiation for organic products, we requested this information because of increasing concern about foodborne illness and growing interest in FDA-approved ionizing radiation as a sanitation or preservation treatment for a wide range of agricultural products.

We received hundreds of thousands of comments from every segment of the organic community—producers, processors, certifying agents, consumers, environmental groups, and retailers—opposing the use of ionizing radiation. These comments indicated that ionizing radiation has been expressly prohibited in all existing organic certification standards, international as well as domestic. Allowing this practice could put domestic producers and handlers at a trade disadvantage, disrupt international markets, and undermine consumer faith in the integrity of the domestic organic label.

Comments suggested alternatives to ionizing radiation for preventing contamination by human pathogens. Alternatives include heat disinfection, refrigeration, moisture and oxygen reduction, packaging, hygienic handling, and appropriate use of disinfectant substances. Although no one suggested that any products might be unavailable if irradiation were prohibited, many commenters expressed the willingness to do without any product that required irradiation. In response to the overwhelming consensus of public comment, this proposal prohibits any use of ionizing radiation for the handling of any organic product in § 205.270(c).

(2) *Incidental Additives.* The first proposal included a provision that permitted the use of incidental additives in processing, except those extracted with a volatile synthetic solvent, if it was necessary for the production of the product. As with previous provisions for practices that could be used only ''if necessary,'' the preamble to the first proposal explained that a determination of necessity was based on site-specific conditions that were described by a producer or handler in an organic system plan or updates to an organic system plan and reviewed by the certifying agent. We requested comments as to the conditions under which an incidental additive might be considered necessary and requested comment as to whether handlers who handle only products sold, labeled, or represented as ''made with certain organic ingredients'' should be exempted from the restriction of using incidental additives only if necessary. An incidental additive was defined as an additive that is present in an agricultural product at an insignificant level, does not have any technical or functional effect in the product, and is not considered an active ingredient. This definition is consistent with 21 CFR 101.100(a)(3)(ii) and is the basis for the definition of an incidental additive in this proposal.

Although thousands of consumers objected to the use of synthetic substances in processed organic products, many others specified that an incidental additive that had been reviewed and approved by the NOSB would be acceptable. Few respondents supported exempting products labeled as ''made with organic ingredients'' from restrictions on the use of incidental additives. The NOSB recommended that documentation be required for use of synthetic incidental additives and that handlers demonstrate progress over time in finding replacements. Organic industry groups also commented that hundreds of incidental additives are currently being used to process organic products and that prohibiting the use of such substances would severely restrict the choices available to consumers and limit the growth of the organic sector. The NOSB recommended several synthetic incidental additives for the National List, recognizing that a wide range of organic products could not be feasiblely manufactured without the use

of incidental additives such as defoaming agents, adjuvants, clarifiers, filtering agents, and equipment cleansers. Therefore, this proposal requires that any incidental additive used to process agricultural products that are intended to be sold, labeled, or represented as ''organic'' or ''made with organic (specified ingredients)'' must be included on the National List of allowed nonagricultural (nonorganic) substances in § 205.605. A product labeled as ''100 percent organic'' could not be produced through the use of any synthetic processing aid.

(3) *Prevention and Control of Facility Pests.* The first proposal addressed the prevention and control of facility pests and authorized the NOP to require such terms and conditions as are determined necessary. These provisions were based on existing organic certification programs and NOSB recommendations. The first proposal included a three-step order of preference, which commenters found to be overly complex and difficult to enforce. This proposal retains similar provisions but simplifies the scheme so that there are only two levels of distinction between preferable and less preferable practices. In this proposal, pest prevention and control methods that do not entail use of biological, botanical, or synthetic substances are equally acceptable, and the producer or handler may only use biological, botanical, or synthetic substances if other approved methods are not effective. Paragraph (c) of § 205.271 parallels the provision proposed in § 205.206(d) addressing crop pest, weed, and disease management. Accordingly, it requires an operator of an organic handling operation who applies any biological, botanical, or synthetic substance for the prevention or control of pests to implement measures to evaluate the effects of repetitive use of the same or similar materials on pest resistance and shifts in pest types.

(4) *Storage Containers.* Sections 205.272 (b)(1) and (b)(2) of this proposal contain provisions similar to the first proposal which prohibit the use of storage containers or bins, including packages and packaging materials, that contain synthetic fungicides, preservatives, or fumigants. These requirements also prohibit the use or reuse of any bag or container that was previously in contact with any substance that could compromise the organic integrity of its contents. This proposal adds a provision to permit the reuse of a bag or container originally used for conventional products if the reusable bin or container has been thoroughly cleaned and poses no risk of prohibited materials contacting organic products. Producers and handlers commented that it is possible and desirable to reuse some kinds of containers if precautions are taken. This modification is consistent with the OFPA, which requires that the organic quality of a product not be compromised.

(5) *Agricultural Fibers.* Some commenters stated that the labeling provisions in the first proposal for processed commodities containing organically produced cotton fibers were excessively restrictive. The OFPA provides the Secretary with the authority to implement standards for organically produced agricultural fibers, including cotton, used for nonfood purposes. This authority includes standards for the production of the agricultural fiber as well as handling standards to regulate the practices and materials that are used in the manufacture of the nonfood commodity. State and private certification agents have made substantial progress in developing and implementing handling standards for organically produced agricultural fibers that are gaining acceptance in the marketplace. We are reviewing the existing certification guidelines and industry practices and anticipate developing standards for processing organically produced agricultural fibers.

Handling—Changes Requested But Not Made

This subpart retains from our first proposal regulations on which we received comments as follows:

(1) *Facility Pest Control Substances.* The first proposal permitted the use of any substance to control facility pests, as long as the intended use was approved by the appropriate regulatory authority and the substance was applied in a manner that prevents it from coming into contact with any organic product. Many consumers objected to this provision and suggested that prohibited substances should never be allowed to be used in any organic operation. However, comments from a number of organic handlers and one industry association stated that, because handling operations must comply with health regulations that require elimination of any pests that may invade food handling facilities, prohibited substances must sometimes be used. The NOSB also acknowledged this possibility in its recommendations, and most organic certification programs similarly allow for such an occurrence, with strict provisions for safeguarding the integrity of organic products. In agreement with these comments, we have proposed a similar allowance in § 205.271(c). The handler must fully document in his or her organic plan the evidence that such a measure was necessary and the measures taken to protect organic products or ingredients from coming into contact with any pest control substance.

(2) *Waxes.* We propose to retain the definition of packaging included in the first proposal, which encompasses waxes used in contact with an edible surface of an agricultural product. A number of commenters disagreed with the inclusion of waxes in the definition of packaging, arguing that waxes should be considered nonagricultural ingredients and, therefore, should be required to appear on the National List of nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients).'' However, the first proposal did require carnauba and other waxes to be on the National List of nonagricultural ingredients allowed for use in organic processed products, and this proposal contains a similar provision. These provisions adequately address the concerns expressed by the commenters that only waxes meeting the criteria for ingredients in organic processed products be permitted. It is appropriate to include waxes in the definition of packaging to ensure that prohibited substances are not added to approved waxes that may be applied to the edible surface of organic products, in accordance with the OFPA, which prohibits use of any packaging materials that contain synthetic fungicides, preservatives, or fumigants.

Subpart D—Labels, Labeling, and Market Information

The Act provides that a person may sell or label an agricultural product as organically produced only if the product has been produced and handled in accordance with provisions of the Act and these regulations. This subpart sets forth labeling requirements for organic agricultural products and products with organic ingredients based on their percentage of organic composition. For each labeling category, this subpart establishes what ''organic'' terms and references can and cannot be displayed on a product package's principal display panel, information panel, ingredient statement, and on other package panels. Labeling is proposed for containers used in shipping and storing organic product and for denoting organic bulk products in market information which is displayed or disseminated at the point of retail sale. Restrictions on labeling organic product produced by exempt operations are described. Finally, this

subpart proposes a new USDA organic seal or shield (hereafter referred to as the USDA Seal) and regulations for display of the USDA seal and display of the seals, logos, or other identifying marks of certifying agents.

The intent of these sections is to ensure that organically produced agricultural products are consistently labeled to aid consumers in selection of organic products and to prevent labeling abuses. These provisions cover the labeling of a product as ''organic'' and are not intended to supersede other labeling requirements specified in various Federal labeling regulations. For instance, we propose that the percent of organic ingredients and the name of the certifying agent be displayed on the information panel of packaged products and that the organic ingredients be identified as ''organic'' in the ingredient statement. The Food and Drug Administration (FDA) has authority to regulate the placement of information on package information panels and, thus, FDA labeling requirements in 21 CFR parts 100 through 169 must be complied with by handler when affixing organic labels to product packages. Display of the USDA Seal and certifying agent seals, logos, or other identifying marks also must be in accordance with those regulations. The requirements of FDA's Fair Packaging and Labeling Act (FLPA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) must be followed. Likewise, the Federal Trade Commission has authority over product advertising and the extent to which a handler or retail food establishment engages in advertising as part of its market information activities. The Federal Trade Commission (FTC) regulations in 16 CFR must be followed. USDA's Food Safety and Inspection Service's (FSIS) Federal Meat Inspection Act, Poultry Products Inspection Act, and Egg Products Inspection Act also have implementing regulations in 9 CFR which must be followed. The labeling requirements specified in this subpart must not be applied in a manner so that they would conflict with the labeling requirements of these and other Federal and State programs.

While this regulation does not require labeling of an organic product as organic, we assume that producers and handlers will choose to label their organic products and display the USDA Seal to the extent allowed in these regulations. They will do this to improve the marketability of their organic product.

In this proposal, assembly, packaging, and labeling of a multiingredient organic product are considered handling activities. The certification of handling operations is covered in subpart C of this regulation. No claims, statements, or marks using the term, ''organic,'' or display of certification seals, other than as provided in this regulation, may be used. A handler which chooses not to use these required and prohibited labeling provisions may not otherwise label or represent a product as organic.

Once a handler makes a decision to market a product as organic or containing organic ingredients, the handler is required to follow the provisions in this subpart regarding use, display, and location of organic claims and certification seals. Handlers who may produce organic ingredients and/or assemble multiingredient products composed of more than 50 percent organic ingredients must be certified as an organic handling operation. Handlers of products of less-than-50-percent organic ingredients do not have to be certified unless the handler actually produces one or more of the ingredients used in the less-than-50-percent product. Repackers who purchase certified organic product from other entities for repackaging and labeling must be certified as an organic operation. Entities which simply relabel a product package would be subject to recordkeeping requirements to show proof that the product purchased prior to relabeling was, indeed, organically produced. Distributors which receive and transport labeled product to market are not subject to certification or any handling requirements of this regulation.

Proposal Description

The general labeling principle employed in this proposal, and to which we think most commenters would subscribe, is that labeling or identification of the organic nature of a product should increase as the organic content of the product increases. In other words, the higher the organic content of a product, the more prominently its organic nature can be displayed. This is consistent with provisions of the Act which establishes the three percentage categories for organic content and basic labeling requirements in two of those categories.

Section 205.300 specifies the general use of the term, ''organic,'' on product labels. Paragraph (a) establishes that the term, ''organic,'' may be used only on labels and in market information of agricultural products and ingredients that have been certified as produced and handled in accordance with these regulations. The term, ''organic,'' cannot be used on a product label for any purpose other than to modify or identify the product or ingredient in the product that is organically produced and handled. Products not organically produced and handled will not be able to use the term, ''organic,'' on any package panel or in market information in any way that implies the product is organically produced.

Categories of Organic Content. The type of labeling and market information that can be used and its placement on different panels of consumer packages will be based on the percentage of organic ingredients in the product. The percentage will reflect the actual weight or fluid volume (excluding water and salt) of the organic ingredients in the product. Four categories of organic content are proposed: 100 percent organic; 95 percent or more organic content; 50 to 95 percent organic content; and less than 50 percent organic content.

100 Percent Organic

For labeling and market information purposes, this proposal allows a ''100 percent organic'' label for an agricultural product that is composed of a single ingredient such as raw, organically produced fruits and vegetables. The product also may be composed of two or more organically produced ingredients, provided that the individual ingredients are organically produced and handled consistent with provisions in subpart C of this regulation. No processing aids may be used in the production of 100 percent organic products. This proposal provides that labeling provisions for ''100 percent organic'' products be the same as provisions for the 95 percent ''organic'' products specified below.

Organic

Products labeled or represented as ''organic'' will contain, by weight (excluding water and salt), at least 95 percent organically produced raw or processed agricultural product. The organic ingredients must be produced using production and handling practices pursuant to subpart C of this regulation. The nonorganic (5 percent or less) ingredients may be composed of nonorganic or nonagricultural substances. The difference between 100 percent organic products and 95 percent-plus products is that the latter may contain up to 5 percent nonorganic or nonagricultural products.

Multiingredient Product: 50–95 Percent Organic Ingredients

For labeling and market information purposes, the third category of agricultural products are multiingredient products containing by weight or fluid volume (excluding water

and salt) between 50 and 95 percent organic agricultural ingredients produced pursuant to these regulations. Such products may be labeled or represented as ''made with organic (specified ingredients).'' By ''specified,'' we mean the name of the agricultural product forming the organic ingredient. The organic ingredients must be produced using substances on the approved National List in subpart G and employing organic production and handling practices consistent with subpart C of this regulation. For instance, breakfast cereal made with 75 percent organically produced and processed wheat and 25 percent other, nonorganically produced grains, raisins, and nuts can be labeled as ''made with organic wheat'' on the principal display panel. To qualify for this organic labeling, the nonorganic ingredients (grains, raisins, and nuts) must be produced and handled without use of the first three prohibited practices specified in paragraph (e) (excluded methods, sewage sludge, or ionizing radiation). However, those nonorganic ingredients may be produced or handled using practices prohibited in paragraphs (e)(4) through (e)(7) (using substances not on the National List; containing added sulfites, nitrates, or nitrites; using nonorganic ingredients when organic ingredients are available; and using organic and nonorganic forms of the same ingredient).

Multiingredient Product: Less Than 50 Percent Organic Ingredients

The final labeling category covers multiingredient products with less than 50 percent organic ingredients (by weight or fluid volume, excluding water and salt). The organic ingredients must be produced using substances on the approved National List in subpart G and employing organic production and handling practices consistent with subpart C of this part. The remaining nonorganic ingredients (50 percent or more of the product) may be produced, handled, and assembled without regard to these regulations (using prohibited substances and prohibited production and handling practices). Organic labeling of these products is limited to the information panel only as provided in § 205.305.

Prohibited Practices. This proposal prohibits labeling of whole products or ingredients as ''organic'' if those products or ingredients are produced using any of the following production or handling practices: (1) Ingredients or processing aids containing or created using excluded methods (genetically modified organisms (GMO)) or the products of excluded methods; (2) ingredients that have been produced using applications of sewage sludge (biosolids) as fertilizer; (3) ingredients that have been processed with ionizing radiation; (4) processing aids not approved on the National List; (5) sulfites, nitrates, or nitrites added to or used in processing of an organic product in addition to those substances occurring naturally in a commodity; (6) use of the phrase, ''organic when available,'' or similar statement on labels or in market information when referring to products composed of nonorganic ingredients used in place of specified organic ingredients; and (7) labeling as ''organic'' any product containing both organic and nonorganic forms of an ingredient specified as ''organic'' on the label. The prohibitions on the use of excluded methods, sewage sludge, irradiated products, and prohibited processing aids are included here to be consistent with the revised National List of Approved and Prohibited Substances in subpart G.

These seven prohibitions apply to the four labeling categories of products and are not individually repeated as prohibited practices in the following sections. Table 1, Prohibited Production and Handling Practices for Organic Labeling, is a summary reference of how the seven prohibited practices must be applied in the production and handling of organic and nonorganic ingredients of products in the four labeling categories.

TABLE 1.—PROHIBITED PRODUCTION AND HANDLING PRACTICES FOR LABELING CATEGORIES

Labeling category	Use excluded methods	Use sewage sludge	Use irradiation	Use processing aids not on national list	Contain added sulfites, nitrates, nitrites	Use organic ingredients when available	Use both organic & nonorganic forms of same ingredient
''100 percent Organic''							
Single/multiingredients completely organic	NO	NO	NO	Use NO Processing Aids.	NO	NO	NO.
''Organic''							
Organic Ingredients (95% or more)	NO	NO	NO	NO	NO	NO	NO.
Nonorganic Ingredients (5% or less)	NO	NO	NO	NO	NO	NO	NO.
''Made with Organic (specified ingredients)''							
Organic Ingredients (50–95%)	NO	NO	NO	NO	NO	NO	NO.
Nonorganic Ingredients (49% or less)	NO	NO	NO	OK	OK	NA*	NA*.
Less-than 50% Organic Ingredients							
Organic Ingredients (49% or less)	NO	NO	NO	NO	NO	NO	NO.
Nonorganic Ingredients (50% or more)	OK	OK	OK	OK	OK	NA*	NA*

* Not applicable.

Calculating the Percentage of Organic Ingredients. This proposal specifies procedures for calculating the percentage, by weight or fluid volume, of organically produced ingredients in an agricultural product labeled or represented as ''organic.''

The organic percentage of liquid products and liquid ingredients will be determined based on the fluid volume of the product and ingredients (excluding water and salt). When a product is identified on the principal display panel or the information panel as being reconstituted with water from a concentrate, the organic content will be calculated on the basis of a single-strength concentration.

Some products may contain both dry and liquid ingredients that are produced organically. In such cases, this proposal provides that the percentage of total organic ingredients will be based on the

combined weight of the dry organic ingredient(s) and the weight of the liquid organic ingredient(s), excluding water and salt. For example, a product may be made using organically produced vegetable oils or grain oils or contain organic liquid flavoring extracts in addition to other organic and nonorganic ingredients. In these cases, the weight of the liquid organic oils or flavoring extracts, less any added water and salt, would be added to other solid organic ingredients in the product, and their combined weight would be the basis for calculating the percentage of organic ingredients. We believe this process provides the most appropriate and least burdensome method for calculating the organic percentage of such multiingredient products.

Only one figure providing the total percentage of all organic ingredients will be shown on the information panel. The total percentage will be displayed on the information panel of the consumer package above or below the ingredient statement with the words, ''contains X percent organic ingredients,'' or a similar phrase. If the total percentage is a fraction, it will be rounded down to the nearest whole number. The percentage of each organic ingredient will not be required to be displayed.

Labeling ''100 Percent Organic'' and ''Organic'' Products. This proposal includes optional, required, and prohibited practices for labeling packages of agricultural products that are ''100 percent organic'' or ''organic'' (at least 95 percent organic). Only products that are composed of a wholly organic single ingredient or entirely of certified organic ingredients may be identified with a percentage number (100 percent) on the principal display panel. Products between 95 and 100 percent organic composition, when identified as ''organic'' on the principal display panel, will be required to state on the information panel the percentage of organic ingredients in the finished product and identify each organic ingredient in the ingredient statement.

The handler may display the following information on the principal display panel, the information panel, and any other part of the package and in market information representing the product: (1) The term, ''100 percent organic'' or ''organic,'' as applicable, to the content of the product; (2) the USDA Seal; and (3) the seal, logo, or other identifying mark of the certifying agent (hereafter referred to as ''seal or logo'') which certified the handler of the finished product. The seals or logos of other certifying agents which certified organic raw materials or organic ingredients used in the product also may be displayed, at the discretion of the handler. If multiple organic ingredients are identified on the ingredient statement, the handler of the finished product that combined the various organic ingredients must maintain documentation, pursuant to subpart B of this regulation, certifying the organic content of the added ingredients.

While certifying agent identifications can appear on the package with the USDA Seal, they may not appear larger than the USDA Seal on the package. There is no restriction on the size of the USDA Seal as it may appear on any panel of a packaged product, provided that display of the Seal conforms with the labeling requirements of FDA and FSIS.

This proposal specifies three labeling practices that will be required if a handler labels a product ''100 percent organic'' or ''organic'' on the principal display panel. If a product is labeled as ''100 percent organic'' the ingredients may also be modified with the term, ''organic,'' but would not have to be so labeled because it is assumed from the 100 percent label that all ingredients are organic. For 95 percent-plus products that contain more than one ingredient, each organic ingredient listed in the ingredient statement must be modified with the term, ''organic.'' Water and salt in the ingredient will not be identified as ''organic.'' Secondly, the total percentage of organic ingredients in the product must be shown on the information panel. The percentage statement should be placed in a manner that it can be viewed in relation to the ingredient statement.

The handler also must display on the information panel the name of the certifying agent which certified the handler producing the finished product. The handler has the option to include the business address or telephone number of the certifying agent. This information must be placed below or otherwise near the manufacturer or distributor's name.

Labeling Products ''Made with Organic (Specified Ingredients)''. With regard to agricultural products ''made with organic (specified ingredients)''—those products containing between 50 and 95 percent organic ingredients—this proposal establishes the following optional, required, and prohibited labeling practices.

Under optional practices, the statement, ''made with organic (specified ingredients),'' may be placed on the principal display panel and other panels of the package. The same statement can also be used in market information representing the product. However, the following restrictions will be placed on the statement, ''made with organic (specified ingredients),'' when it appears on the principal display panel: (1) The statement cannot list more than three organic ingredients in the product; (2) the statement cannot appear in print that is larger than one half (50 percent) of the size of the largest print or type appearing on the principal display panel; and (3) the statement must appear in its entirety in the same type size, style, and color without highlighting. Display of the statement, ''made with organic (specified ingredients),'' on other panels must be similarly consistent with the size of print used on those panels. These restrictions are consistent with FDA regulations and similar to the recommendations of the National Organic Standards Board (NOSB). This provision will help assure that the statement, ''made with organic (specified ingredients),'' is not displayed in such a manner as to misrepresent the actual organic composition of the product.

We also propose that, at the handler's option, the certifying agent's seal or logo may be displayed on the principal display panel or other package panel.

Packages of products labeled as ''made with organic (specified ingredients)'' will be required to display on the information panel the total percentage of organic ingredients in the product and modify each organic ingredient listed in the ingredient statement with the term, ''organic.'' The percentage of organic ingredients must be displayed so that it can be viewed in relation to the ingredient statement.

The name of the certifying agent which certified the handler of the finished product must be displayed below or otherwise near the manufacturer or distributor's name. The statement may include the phrase, ''Certified organic by * * *'' or ''Ingredients certified as organically produced by * * *'' to help distinguish the certifying agent from the manufacturer or distributor. At the handler's option, this label may include the business address or telephone number of the certifying agent which certified the handler of the finished product.

Labeling Products with Less Than 50 Percent Organic Ingredients. The final labeling category covers packaged multiingredient agricultural product containing less than 50 percent organic ingredients.

Handlers of ''less than 50 percent'' multiingredient products, who choose to declare the organic nature of the

product, may do so only on the information panel by declaring the total percentage of organic ingredients in the product and, in the ingredient statement, modifying the organic ingredients with the term, ''organic.'' The percentage statement must be displayed so that it can be viewed in relation to the ingredient statement.

Products composed of less than 50 percent organic content cannot display the USDA Seal or any certifying agent's seal or logo anywhere on the product package or in market information.

Handlers of such products will be subject to this regulation in the following ways. Those handlers who only purchase organic and nonorganic ingredients and assemble a finished product of less than 50 percent organic content do not have to be certified as organic handlers. They will be responsible for appropriate handling and storage of the organic ingredients prior to product assembly and for maintaining records verifying the organic certification of the ingredients used in the product. To the extent that the packaging process includes affixing the label to finished product package, those handlers will be responsible for meeting the labeling requirements of this subpart. Handlers who produce an organic ingredient prior to assembly into a finished product, even though the finished product contains less than 50 percent organic content, and must be certified as to the source of the organic ingredient(s). The nonorganic ingredients may be produced, handled, and assembled without regard to the requirements of this part.

The handler who affixes the label to the product package will be responsible for calculating the percentage of organic ingredients in an organic product. As part of the certifying agent'' annual certification of the handler, the certifier will verify the calculation and labeling of packages.

Table 2, *Labeling Consumer Product Packages,* provides a summary of the required and prohibited labeling practices for the four labeling categories.

TABLE 2.—LABELING CONSUMER PRODUCT PACKAGES

Labeling category	Principal display panel	Information panel	Ingredient statement	Other package panels
''100 percent Organic'' (Entirely organic; whole, raw or processed product).	''100 percent organic''	''100% Organic''	If multiingredient product, identify each ingredient as ''organic''.	''100 percent Organic''.
	USDA Seal and Certifying agent sets(s).	Certifying agent name (required); business address, tele. # (optional).	.....	USDA Seal and Certifying agent seal(s).
''Organic'' (95% or more organic ingredients).	''Organic''	''*X*% Organic Ingredients''.	Identify organic ingredients as ''organic''.	''Organic''.
	USDA Seal and Certifying agent seals(s).	Certifying agent name (required); business address, tele. # (optional).	.....	USDA Seal and Certifying agent seal(s).
''Made with Organic (specified ingredients)'' (50 to 95% organic ingredients).	''Made with organic (specified ingredients)''.	*''X% Organic Ingredients''.*	Identify organic ingredients as ''organic''.	''Made with organic (specified ingredients)''.
	Certifying agent seal of final product handler.	Certifying agent name (required; business address, tele. # (optional).	Identify organic ingredients as ''organic''.	''Made with organic (specified ingredients)''.
	Prohibited: USDA Seal ..	*Prohibited: USDA Seal* ..	.....	*Prohibited: USDA Seal.*
Less-than 50% Organic Ingredients (49% or less organic ingredients).	*Prohibited: Any reference to organic content of product.*	''*X%* Organic Ingredients''.	Identify organic ingredients as ''organic''.	*Prohibited: Any reference to organic content of product.*
	Prohibited: USDA Seal & Certifying agent seal.	*Prohibited: USDA Seal & Certifying agent seal.*	.....	*Prohibited: USDA Seal & Certifying agent seal.*

Misrepresentation in Labeling of Organic Products. The labeling requirements of this proposal are intended to assure that the term, ''organic,'' and other similar terms or phrases are not used on a product package or in marketing information in a way that misleads consumers as to the contents of the package. Thus, we intend to monitor the use of the term, ''organic,'' and other similar terms and phrases. Should we find that terms or phrases are being used on product packages to represent ''organic'' when the products are not produced to the requirements of this regulation, we will proceed to restrict their use.

After consideration of alternative labeling terms that handlers might wish to use to qualify or modify the term, ''organic,'' we have determined that handlers may not qualify or modify the term, ''organic,'' using adjectives such as, ''pure'' or ''healthy,'' *e.g.,* ''pure organic beef'' or ''healthy organic celery.'' The term, ''organic,'' is used in labeling to indicate a certified system of agricultural production and handling. Terms such as ''pure,'' ''healthy,'' and other similar adjectives attribute hygienic, compositional, or nutritional characteristics to products. Use of such adjectives misrepresents products produced under the organic system of agriculture as having special qualities as a result of being produced under the organic system. Furthermore, use of such adjectives would incorrectly imply that products labeled in this manner are different from other ''organic'' products that are not so

Moreover, ''pure,'' ''healthy,'' and other similar terms are regulated by FSIS and FDA. These terms may be used only in accordance with the labeling requirements of FDA and FSIS. For example, the regulations implemented by FSIS, 9 CFR 317.363, define the terms, ''healthy,'' ''health,'' and similar derivations and the conditions of use as a nutritional claim. Also, according to FSIS regulations, 9 CFR 317.8(b)(34), the term, ''pure,'' as well as the terms, ''all,'' ''100 percent,'' and similar terms, may only be used to indicate that a single ingredient product is composed of 100 percent of the product ingredient and contains no other ingredients. The term, ''healthy,'' is regulated by FDA (21 CFR

101.14) and can be used, with documentation, only to indicate or characterize a relationship of the product to a disease or health-related condition. The prohibition on use of these terms to modify ''organic'' does not otherwise preclude their use in other labeling claims.

We also intend to monitor the use of the term, ''organic,'' in corporate or company names and seek additional guidance from the FTC. We do not believe that the term, ''organic,'' in a brand name context inherently implies an organic production or handling claim or inherently constitutes a false or misleading statement.

The determination as to whether the use of the term, ''organic,'' in a brand name conveys a message about the product's attributes must be made by the Secretary. We will monitor use of the term, ''organic,'' in product and company names at this time. However, if we find that the term is being used in a false or misleading way to misrepresent the organic nature of the product, we have the authority under section 6519(b) of the Act to take action against such use. Such determinations and actions will be taken on a case-by-case basis.

Labeling of Products Shipped in International Markets. Domestically produced organic products intended for export may be labeled to meet the requirements of the country of destination or any labeling requirements specified by a particular foreign buyer. For instance, a product label may require a statement that the product has been certified to, or meets, certain European Union organic standards. Such factual statements regarding the organic nature of the product will be permitted. However, those packages must be exported and cannot be sold in the United States with such a statement on the label because the statement indicates certification to standards other than are required under this program. As a safeguard for this requirement, we require that shipping containers and bills of lading for such exported products display the statement, ''for export only,'' in bold letters. Handlers also will be expected to maintain records, such as bills of lading and U.S. Customs Service documentation, showing export of the products. Only products which have been certified and labeled consistent with the requirements of the National Organic Program (NOP) may be shipped to international markets without marking the shipping containers ''for export only.''

Organic product produced under a foreign country's or international association's organic standards deemed equivalent to these standards and certified by a certifying agent accredited by the Secretary may be imported into the United States provided that the product labels are consistent with the requirements of this subpart. Any labeling on the product package or in market representation cannot imply that the product is also certified to other organic standards or requirements that are more restrictive than this national program. These provisions are consistent with international standards and will facilitate international trade of organically produced products and, thus, benefit the global organic industry.

Labeling Nonretail Containers. Section 205.306 provides for labeling nonretail containers used to ship or store raw or processed organic agricultural products that are labeled ''100 percent organic,'' ''organic,'' and ''made with organic (specified ingredients).'' These labeling provisions are not intended for shipping or storage containers that also will be used in displays at the point of retail sale. They would be used for easy identification of the product to help prevent commingling with nonorganic product or handling of the product which would destroy the organic nature of the product (fumigation, etc.). Retail containers will have to meet labeling provisions specified in § 205.307.

Containers used only for shipping and storage of any product labeled as containing 50 percent or more organic content may, at the handler's discretion, display the following information: (1) The name and contact information of the certifying agent which certified the handler of the finished product; (2) the term, ''organic,'' modifying the product name; (3) any special handling instructions that must be followed to maintain the organic integrity of the product; and (4) the USDA Seal and the appropriate certifying agent seal. This information is optional if handlers believe display of the information helps ensure special handling or storage practices which are consistent with organic practices.

Containers used for shipping and storage of organic product must display a production lot number if such a number is used in the processing and handling of the organic product being shipped or stored. The lot number must be included for inventory control and quality assurance purposes. To help assure export of organic product produced and labeled to foreign specifications, the shipping containers and shipping documents (bills of lading) must be marked with the phrase, ''for export only,'' in bold letters. The handler also must maintain records showing export of the product to a foreign country.

Much of the required information may overlap information that the handler normally affixes to shipping and storage containers or information that is required under other Federal labeling regulations. Provisions in this proposal do not take precedence over food safety or quality control provisions which may be required for specified products or types of products covered by such Federal regulations. There are no restrictions on size or display of the term, ''organic product,'' or the certifying agent seal unless otherwise required by other Federal or State statutes.

Labeling Products at the Point of Retail Sale Section 205.101(b)(2) of subpart B on Applicability provides regulations regarding the certification of retail food establishments under this program. Those operations are subject to labeling and market information requirements concerning products offered to consumers at the point of retail sale. Such labeling and market information must truthfully represent the organic nature and handling of the product.

Section 205.307 applies to organically produced products that are not prepackaged prior to sale and are presented in a manner which allows the consumer to select the quantity of the product purchased.

To be labeled as ''100 percent organic'' or ''organic'' at the point of retail sale, the processing and assembly of such products must be carried out by a certified manufacturing facility for distribution to a retail food establishment. For instance, a tossed salad may be labeled as ''100 percent organic tossed salad'' or ''organic tossed salad'' (consistent with the percentage of organic ingredients in the salad) provided the salad and ingredients have been produced and assembled under organic certification. If the multiingredient product is identified as ''organic'' at the point of retail sale, any ingredient statement displayed at retail sale must identify the organic ingredients as ''organic.'' The retail materials may also display the USDA Seal and the seal or logo of the certifying agent. If shown, the certifying agent seal must not be larger than the USDA Seal.

Using the same example, a product made with 95 percent or more certified organic salad components but which is assembled at an uncertified operation may be labeled ''tossed salad made with organic (specified ingredients).'' The retail food establishment may not

display the USDA Seal or the seal or seals of cerftifying agents involved in ingredient certifications because the final assembly of the product was not certified pursuant to the handling requirements of this regulation.

Our position on the applicability of these regulations to different business entities is more completely explained in subpart B, Applicability, of this regulation.

''Section 205.308 addresses processed products ''made with organic (specified ingredients)'' that are not prepackaged prior to sale and are presented in a manner which allows the consumer to select the quantity of the product purchased. These products will include, but will not be limited to, multiingredient products containing between 50 and 95 percent organic ingredients. Retail displays, display containers, and market information for such products may display the phrase, ''made with organic (specified ingredients)'' provided that the product has been assembled by a manufacturing facility certified pursuant to this regulation. Up to three organic ingredients may be identified in the statement. If such statement is declared in market information at the point of retail sale, the ingredient statement must identify the organic ingredients as ''organic.'' Retail display and market information of such bulk products cannot use the USDA Seal but may display the seal or logo of the certifying agent which certified the finished product, provided that assembly of the product was carried out at a certified manufacturing facility. The certifying agent's seal or logo may be displayed at the option of the retail food establishment. If such a product has not been assembled at a certified manufacturing facility, the retail display and market information may not identify the product as ''made with organic (specified ingredients).''

Prepared food products containing less than 50 percent organic ingredients at retail sale may not be identified as organic or containing organic ingredients. The USDA Seal and any certifying agent seal or logo may not be displayed.

Labeling Products Produced on Exempt or Excluded Operations. This proposal provides limited organic labeling provisions for organic product produced or handled on exempt and excluded operations. Such operations would include retail food establishments, certain manufacturing facilities, and production and handling operations with annual organic sales of less the $5,000. They are discussed more thoroughly in subpart B, Applicability.

Under this proposal, any such operation that is exempt or excluded from certification, or which chooses not to be certified, may not label its products in a way which indicates that the operation has been certified as organic. Primarily, this means that the exempt or excluded operation may not display the USDA Seal or any seal or logo of a certifying agent. Any packaged organic product from an exempt or excluded operation may not use the labeling terms ''100 percent organic,'' or ''organic,'' or ''made with organic (specified ingredients),'' on the principal display panel. Those labeling terms are reserved for products produced by certified operations. The organic representation of exempt or excluded operation products may only be made on the information panel where the organic percentage can be displayed and the organic ingredients identified as ''organic.''

Retail displays and market representation of such products may not indicate that the product has been certified as organic. For instance, a whole, raw, organic product marketed directly to consumers at a farmers market or roadside stand as ''organic apples'' or ''organic tomatoes.'' However, no terms may be used which indicate ''certified'' organic apples, etc. No organic seal or logo may be displayed with the product at the point of retail sale.

We propose these restrictions simply as truth in labeling provisions because use of terms or phrases reserved for certified operations and products and display a certification seal will indicate that the product has been certified. We believe this requirement will help differentiate between certified and not certified products and help maintain the integrity of certified products while providing limited organic labeling opportunities for exempt and excluded operations.

Finally, this rule proposes that exempt organic producers cannot sell their product to a handler for use as an ingredient or for processing into an ingredient that will be labeled as ''organic'' on the information panel. However, this restriction is raised for public comment in subpart B, Applicability, of this part.

Small producers or handlers who qualify for exemption but who choose to be certified pursuant to these regulations can label their product as certified organic and can sell that product to certified handlers for further processing as an organic ingredient.

USDA Seal. This proposal introduces a new, redesigned, USDA Seal, that can be placed on consumer packages, displayed at retail food establishments, and used in market information to show that products have been produced and handled in accordance with these regulations. The Seal can only be used to identify raw and processed products that are labeled as ''100 percent organic'' or ''organic.'' It cannot be used for products labeled as ''made with organic (specified ingredients)'' (50 to 95 percent organic ingredients) or on multiingredient products with less than 50 percent organic ingredients.

The USDA Seal presented in this proposal will consist of the phrase, ''USDA Certified Organic,'' on a shield or badge design. When used, the seal must be the same form and design as shown in figure 1 of § 205.310 of this proposal. The seal must be printed legibly and conspicuously. On consumer packages, retail displays, and labeling and market information, the Seal may be printed on a white, light colored, or transparent background with contrasting dark colored words and shield outline or on a dark colored background with contrasting words and shield outline in one or two light colors. The Seal also may be printed in the colors red, white, and blue as follows: a white background, with dark blue shield outline, and red words. The choice of color scheme is left to the discretion of the producer, handler, or retail food establishment based on other colors on the product package and other considerations.

Labeling—Changes Based On Comments

This subpart differs from our first proposal in several respects as follows:

(1) *Use of terms other than ''organic.''* The first proposal stated that informational statements which imply ''organic'' production and handling should be used only on products that are produced and handled in accordance with these regulations. The proposal identified several informational statements commonly referred to as ''eco-label'' or ''green'' terms and phrases such as: ''produced without synthetic fertilizers,'' ''pesticide free farm,'' ''no drugs or growth hormones used,'' ''raised without antibiotics,'' ''ecologically produced,'' ''sustainably harvested,'' etc. We asked for comments on these and other terms or phrases which directly or indirectly imply that a product was organically produced and handled.

Commenters favored use of ''eco-label'' and ''green'' terms and phrases on any product labels. The general consensus expressed in the comments is

that producers and handlers should be able to make claims about their product provided the claims are truthful.

While commenters did not oppose the use of eco-label terms or phrases on nonorganic products, they made it clear that the term, ''organic,'' should only be used on products produced and handled in accordance with these regulations. Several commented that consumers respond favorably to the term, ''organic,'' when used on a product label, and, therefore, proper use of the term must be closely protected.

We also received several comments regarding use of the terms, ''biological'' and ''ecological,'' on product labels. A few comments indicated that the terms should be allowed on nonorganic products to truthfully describe an alternative agricultural system under which the product was produced or processed. However, most commenters opposed use of the terms as substitutes for the term ''organic'' on product labels.

We agree with the majority of comments received on this subject, and we, therefore, propose to regulate the term, ''organic,'' and no other terms. We propose that the term, ''organic,'' may only be used on labeling and market information of products that are produced and handled in accordance with these regulations. We understand that the terms, ''ecological'' and ''biological,'' are a special case in that they are used synonymously with the term, ''organic,'' in other countries. However, they cannot be used interchangeably with the term, ''organic,'' in this country. These terms may be used as eco-labels at this time. However, we will proceed to restrict use of these or any other terms if we find that they are used on product packages in the United States to represent ''organic'' when the products are not produced to the requirements of this regulation.

(2) *100 percent organic category.* Our first proposal did not provide for a ''100 percent organic'' category because that level of organic composition is not specifically provided for in the Act. While the Act and the first proposal provide for a labeling category of 95 percent or higher organic content, commenters appealed for a labeling category for product that is 100 percent organic. Many suggested that being able to use the term, ''100 percent,'' will give handlers added incentive to use only certified ingredients in multiingredient products. Some commenters suggested that if a product is composed only of organic ingredients, with no additives or other substances, it should be allowed to be labeled and represented in market information as 100 percent.

We agree that a ''100 percent organic'' labeling category may increase the effectiveness of marketing efforts and may provide incentives for handlers to use more certified organic ingredients in their multiingredient products. Therefore, this proposal will allow the term, ''100 percent organic,'' to be used on labels affixed to or market information representing raw or processed organic products that are composed entirely of organically produced agricultural product.

(3) *Identification of private certifying agents.* Under the first proposal, identification of private certifying agents was not permitted on the principal display panel with the USDA Seal and the State organic seal. While a few commenters suggested that only the USDA Seal should be displayed on the principal display panel, the majority of those commenting on this topic requested that private certifying agent seals be displayed on an equal basis with a seal of the appropriate State's organic program. Although the number of State certifying agents is relatively small, private certifying agents believe that State organic programs and State certifying agents may implement measures in States that work against the interests of private certifying agents. The Department believes those concerns to be unfounded. Under the NOP, the Secretary will approve all State organic programs and accredit all State certifying agents. However, any of those programs or agents that might discriminate or work against the interests of private certifying agents in the State would not be approved by the Secretary.

Some commenters suggested that many private certifying agent seals are widely recognized and respected and their seals influence consumer choices in product purchases. It is appropriate that private certifying agents be afforded the same treatment with regard to labeling as the State certifying agent. We agree with commenters' requests for equal treatment of certifying agents and that certifier seals may have marketing potential in some areas. Therefore, we specify in this proposal that a private certifying agent's seal or logo can be displayed to the same extent as the seal of a State certifying agent. This change is reflected throughout this subpart.

(4) *Use of a certifying agent's seal or logo.* Many commenters believe that the certifying agent's seal, logo, or identifying mark shown on ''100 percent organic'' and ''organic'' products should be the seal or mark of the certifying agent that certifies the handler of finished product. Commenters also stated that labels should not be used to misrepresent one product as being more organic than another product, which might happen if multiple seals are displayed on one product package and only two are displayed on a competing product package. While we understand the commenters' points, we believe that display of certifying agent seals on products labeled ''100 percent organic,'' ''organic,'' and ''made with organic (specified ingredients)'' should remain optional for handlers. If two or more certifying agents are involved in certifying raw organic agricultural product and organic ingredients used in a finished product, the seals or marks of those certifying agents may be displayed, at the discretion of the handler. There should be only two restrictions to using multiple certifying agent seals: (1) The seal of the certifier of the handling operation producing the finished product should be displayed; and (2) only the seals of those certifying agents actually involved with certification of the product or ingredients may be displayed. For instance, a private certifying agent may certify a product assembled using organic ingredients produced in Texas and certified by the Texas State certifying agent. The product package may, at the handler's option, display the Texas State agent's seal in addition to the seal of the private certifying agent which certified the operation creating other organic ingredients and creating the finished product. Likewise, display of a seal of a foreign country's organic program or foreign certifying agent will be permitted only if the foreign agent certified the finished product or a product ingredient.

Some commenters say that display of two State agent seals may confuse consumers. However, we do not believe it is likely that handlers will choose to display multiple certifying agent seals to misrepresent a product. We also do not believe that possible consumer confusion from display of multiple seals should take precedence over the handler's right to provide product information. If multiple certifying agent seals or marks are displayed on a product package or in market information, the handler or retail food establishment must maintain appropriate records showing proof of all organic certifications.

(5) *Display of certifying agent name and business address.* Commenters also suggested that the certifying agent's name and business address be displayed adjacent to identification of the handler or distributor of products labeled ''organic'' and ''made with organic

(specified ingredients).'' The commenters stated that such information should be available for consumers who may have questions about the organic nature of a product or product ingredients. We agree that the name of the certifying agent should be included on a product package but believe that display of the business address or telephone number should be optional to the handler who assembles the finished product and affixes the label on the package. If a consumer wants to inquire about the organic nature of a purchased product, the consumer can obtain contact information through the certifying agent database listed on the NOP homepage. Finally, to clearly identify the information provided, the statement, ''Certified organic by * * *'' or ''Ingredients certified as organically produced by * * *,'' may be used to distinguish the certifying agent from the manufacturer or distributor of the product.

The statement and agent identification is intended for information purposes only and is not to promote the organic nature of the product. The certifying agent identification may be placed below the manufacturer or distributor information and must not interfere with display of that information.

(6) *Size of certifying agent seal.* There was a general consensus among commenters that the seals of State and private certification agents should not be larger than the USDA Seal. To emphasize the market value of such a national organic seal and maintain some consistency of treatment with regard to the different organic content categories, we propose that State and private certifying agent seals can be the same size as but must not exceed the size of the USDA Seal on any package label or in market information. The size of the USDA Seal on a package is left to the discretion of the handler.

(7) *Displaying the percentage of organic ingredients.* The first proposal permitted use of the word, ''organic,'' in the ingredient statements to modify those ingredients that were produced and handled pursuant to these regulations, but did not require the percentage of organic ingredients to be displayed on the label. Most all commenters responding to this labeling issue stated that identification of organic ingredients as ''organic'' will encourage handlers to increase the organic composition of multiingredient products. However, some commenters did not favor any use of the word, ''organic,'' on packages of multiingredient products containing less than 50 percent organic ingredients. Some commenters also suggested that including the total percentage of organic content adjacent to the ingredient statement (in which the organic ingredients are identified) would give relevance to the ingredient statement. We concur with commenters' recommendations about the display of the total percentage of organic content and propose that the percentage of organic ingredients be placed on the information panel. The percentage statement and the ingredient statement should be shown in a way that indicates the relationship of the information. If a product is labeled ''100 percent organic,'' all ingredients (except water and salt), by definition, would have to be certified organic ingredients, and each ingredient may be but would not have to be identified as ''organic.'' Identification of organic ingredients would be required for products labeled ''organic'' and ''made with organic (specified ingredients),'' and for products containing less than 50 percent organic ingredients. We did not change the identification of organic ingredients for products containing less than 50 percent organic ingredients because we believe the uses of the term on the information panel and ingredient statement of such product packages do not imply that the product is organic.

(8) *Labeling of products containing 50–95 percent organic ingredients.* The first proposal specified that products with 50–95 percent organic content could use ''made with certain organic ingredients'' on the label. Many commenters suggested that the word, ''certain,'' may appear confusing to consumers and that a stronger statement is needed to identify the organic nature of the product. One commenter sought clarification of whether the term, ''certain,'' is a substitute for the name of the ingredient in a single-ingredient product. Many requested that the statement be changed to allow specific identification of the organic ingredients on the principal display panel. Because that is the panel first and most often observed by consumers, the commenters indicated that the information presented on the principal display panel should be clear and accurate to assist consumers in making their purchasing decisions.

After review of the comments, we believe that, if the statement is going to be displayed on the principal display panel, it should state the specified organic ingredient in the product; *e.g.,* ''made with organic (specified ingredients).'' Replacing the word, ''certain,'' with the actual organic commodity name or organic ingredient will add the specificity sought by commenters and assist consumers in making more informed choices. Under this proposal, the statement, ''made with organic (specified ingredients),'' must be used on the principal display panel and on other package panels of a product containing between 50 and 95 percent organic ingredients.

Several commenters suggested that the size of the letters in the phrase be limited to a fraction of the size of the product name as it appears on the principal display panel. They stated that limiting the size of the letters will keep the statement from making the product appear more organic than products with 95 percent organic ingredients. For instance, if a product contains 55 percent organic ingredients and the statement, ''made with organic (specified ingredients),'' is displayed on the principal display panel in large, bold letters, the product may appear more organic than a 97-percent product simply labeled ''organic.'' Commenters recommended letter sizes from one-half to three-fourths the size of the product name as it appears on the principal display panel.

We also believe that the labeling for these products should not use typeface or letter sizes which would mislead consumers. FDA labeling requirements in 21 CFR 101.3(d) specify that required statement of identity of the product shall be in a size most reasonably related to the largest printed matter on a panel. FDA enforces ''reasonably related'' as being one half the size of the largest printed matter, which is usually the product name. Therefore, to be consistent with FDA labeling requirements, we have established the print size of the statement, ''made with organic (specified ingredients),'' to be not more than 50 percent, or one half, of the largest print size appearing on the principal display panel. This print size is consistent with the recommendation of many commenters but is smaller than the 75 percent recommended by the NOSB. We propose that the statement, ''made with organic (specified ingredients),'' appear in only one print style and color, without highlighting.

We believe that these additional restrictions on display of the statement will enable the message to be delivered and yet provide some structure and consistency to display of the statement. It is our intention that the statement not be used to disproportionately dominate the principal display panel or other panels and not be used to misrepresent the organic nature of the product.

(9) *Limiting the number of organic ingredients listed.* Some commenters suggested limiting the number of organic ingredients that could be

included in the statement ''made with organic ingredients.'' This topic was the subject of much NOSB deliberation and public discussion. Commenters reasoned that if the list of organic ingredients became too long, the product could appear to be more organic than ''95 percent'' products. For instance, a product could have 10 organic ingredients, but those 10 ingredients may comprise only 51 percent of the product. The consensus of comments suggested that the statement should be limited to three organic ingredients, which is the industry standard. We believe their recommendation has merit and, therefore, propose that up to three organic ingredients can be shown in the statement. We encourage additional comments on the maximum number of ingredients that should be allowed to appear in the statement on the principal display panel. Commenters should provide reasons for the number they recommend.

(10) *Qualifications for display of the USDA Seal.* In the first proposal, we permitted the display of the USDA seal on products with 50 percent or more organic ingredients. Commenters objected. They overwhelmingly endorsed a high organic content standard for a product to be labeled as ''organic.'' They believe products containing less than 95 percent organic ingredients do not have sufficient organic content to justify an ''organic'' label on the principal display panel, and should not be so labeled under the NOP regulations. Commenters also stated that display of the USDA Seal will be very desirable. Many stated that a prohibition on display of the USDA Seal on 50-to-95-percent products would encourage handlers who assemble multiingredient products to use more organically produced ingredients and fewer nonorganic ingredients. They suggested that the USDA Seal and the certifying agent's seal or logo not be displayed on any package panel of products ''made with organic (specified ingredients)'' or on products with less than 50 percent organic ingredients.

We agree that some distinction should be made between 95 percent-plus organic products and the 50–95 percent organic products. Handlers of 95 percent-plus organic products may display both the USDA Seal and the certifying agent seal or logo on the principal display panel of the product. The commenters propose that handlers of 50–95 percent organic products not be allowed to display either seal on the principal display panel. However, we believe that, because handlers of 50–95 percent organic product are required to be certified under this program, it is appropriate that they should be allowed to display some evidence of that certification. We propose, therefore, that handlers of 50–95 percent organic product may display the seal or logo of the certifying agent which certified the finished product. Display of the USDA Seal will still be restricted to only 100 percent organic products and to 95 percent-plus products. We believe this provision will provide more equitable treatment for handlers of 50–95 percent products who are required under this regulation to obtain and maintain organic certification in order to label their organic product. It will also maintain a distinction between the two product levels by continuing the restriction on display of the USDA Seal. We believe that, while display of the USDA Seal is less likely to be an incentive for handlers of products at the lower end of the 50 to 95 percent range of organic content, handlers of products at the higher end of the 50 to 95 percent organic content range may be encouraged to increase the organic content in order to display the USDA Seal.

An organic product produced or handled by an exempt or excluded operation, including those with less than $5,000 annual organic sales, may not display the USDA Seal or the seal of a certified agent because the operation has not been certified. Even if the organic content of the product is 95 percent or higher, the product still cannot be labeled as ''certified'' organic or marketed using an organic seal or logo.

(11) *Design of the USDA Seal.* The final change prompted by comments is redesign of the USDA Seal. The Seal in the first proposal was a triangular shape behind a circle of recycling arrows around a globe figure with the word, ''organic,'' printed diagonally across the globe. That proposed seal was opposed by hundreds of commenters. Comments included: The triangle resembles a radioactive warning symbol or fallout shelter sign; the diagonal line across the circle appears to be the universal ''no'' sign (such as ''no walking,'' ''no smoking''); the globe design doesn't show up; the globe design implies an international program; the design is too busy; simplify the design; use the words, ''certified organic''; use a text logo; the seal will be too costly to produce; and the triangle points will puncture or tear plastic when printed.

Given the overwhelming negative response to the first seal, we propose a simplified design composed of the words, ''USDA CERTIFIED ORGANIC,'' inside a shield or badge design. This design is consistent with comments requesting simplicity and use of the words, ''certified organic.'' At the request of commenters, this proposal provides for labeling on transparent material. We believe the proposed basic dark on light or light on dark requirement is broad enough to allow handlers the flexibility needed to match color schemes compatible with their product packages. The alternative red, white, and blue color scheme offers handlers what consumers may identify as a more official or patriotic display of the Seal. We believe it is important that the Seal be displayed in a consistent manner, within general light/dark guidelines so that the Seal becomes easily recognizable to consumers.

Labeling—Changes Requested But Not Made

Comments reflecting different opinions on the same topic are covered above (*e.g.,* the number of organic ingredients listed on the principal display panel, the size of ''organic'' letters on the principal display panel, a recommended redesign of the USDA Seal, etc.). Obviously, not all such conflicting recommendations can be accepted. Two comments were received which are not accepted but which we believe warrant further consideration by the public and the organic community. We request additional comments regarding the following two recommendations. Commenters should specify their recommendation regarding each topic and provide reasons for their recommendation.

(1) *Changing the ''organic'' threshold for multiingredient products.* At least one commenter suggested that the 50–95 percent labeling category sets too low a threshold for organic labeling of multiingredient products. The commenter suggested that, for increased international acceptance of USDA standards, the lowest acceptable percentage for receiving an organic label should be 70 percent organic ingredients, based on the European Union (EU) standard which now requires a minimum of 70 percent organic ingredients for the product to be labeled as ''organic'' (or, ''biological'' or ''ecological'').

The EU standard allows products with a 70 percent organic content to be labeled as ''organic,'' where our proposal will require at least 95 percent organic content before a product could be labled as ''organic.'' This 95 percent standard is in the Act. Where the two standards differ is that the EU standard doe not have a ''made with organic (specified ingredients)'' category proposed in this rule.

While the Act establishes a 50-percent minimum ingredient content, that percentage can be adjusted upward if doing so would further the purposes of the Act. To do so, however, the Secretary must have good cause and justification for establishing a higher minimum organic ingredient content. In other words, we could raise the minimum organic ingredient content threshold to 70 percent, redefining two of our four categories. The four categories would be: less than 70 percent, 70–95 percent, greater than 95 percent, and 100 percent. Under this scenario, the prohibitions on excluded methods, irradiation, and sewage sludge would not apply to the nonorganic ingredients of products with less than 70 percent organic content. At the same time, these products would only be able to list the organic ingredients on the information panel. The ''made with organic ingredients'' category, to which the prohibition would apply, would be 70–95 percent organic content. The only products that would get the ''organic'' designation would still be those with at least 95 percent organic content.

Because we find no compelling reason to raise the 50-percent minimum ingredient content threshold established in the Act, we have not accepted the commentor's recommendation in this proposal. However, if comments on this proposal suggest an appropriate justification, the minimum ingredient content threshold could be raised in the final rule.

(2) *Minimum content requirements for organic ingredients.* One commenter suggested that a minimum percentage of the entire product weight be established to qualify for a single ingredient to be included in the statement, ''made with organic (specified ingredients).'' The commenter suggested that this would help prevent misrepresentation of the organic nature of a product. The commenter suggested that the minimum content for any ingredient should be 15 percent. The commenter did not justify the 15-percent minimum (as opposed to another minimum percentage). Because such a recommendation could prevent important ingredients from being specified on a product label, we have not incorporated the comment in this proposal. However, we believe the comment may have merit. One factor in establishing a minimum percentage for any individual ingredient listed on the principal display panel would be the established minimum percentage for all organic ingredients in a product, the question raised in the paragraph above. For instance, if the minimum percentage of all ingredients is established at 70 percent to conform to EU standards, should there be a minimum percentage for any individual organic ingredient that could be listed on the principal display panel as one of three organic ingredients in the product? Would such a labeling restriction prevent identification of an important organic ingredient from being displayed on the principal display panel?

Commenters on questions (1) and (2) should state whether they think the recommendations would further the marketing of organic products and, if so, clearly state the recommended percentage for each question and the reasons for their opinions regarding each issue.

(3) *Labeling requirements for small operations.* A majority of those who commented on the exemption for small operations (less than $5,000 organic sales) in the first proposal stated that such operations are not exempt from labeling requirements under the Act. In this proposal, we provide limited labeling provisions which prohibit exempt and excluded operations, including those with less than $5,000 in annual organic sales, from labeling their products in a way that indicates the operations or the products have been certified as organic. These provisions will not allow such operations to use labeling terms and organic seals and logos specified for certified operations. We believe those terms, logos and seals should be reserved for operations and products that are certified under these regulations.

Labeling—Additional Provisions

Upon further review of the label and market information provisions in the first proposal, we propose the following additions and changes.

(1) *Display of a State organic seal.* Under the first proposal, each State organic certification program would have been allowed to display a seal or logo of its State organic program. The first preamble stated that it was appropriate for a State to have a seal representing its organic program, thus allowing product produced under that program to bear the State's seal.

Currently, 13 State departments of agriculture (or other State agency) and approximately 40 private agents certify to a variety of private and State organic requirements. After establishing a policy which more clearly defines the criteria for approval of a State organic program, we believe that, in the interest of consistent and uniform national standards, product packages should not display the seal of a State organic program if the seal is different from the seal or mark used by the State's organic certifying agent.

This determination is based on a proposed change in State programs. A State organic program will be approved by the Secretary for specific, need-based reasons particular to that State (see State Programs under subpart G). To establish and maintain uniform national standards, States will not be authorized to implement more restrictive organic standards simply to promote State products that are ''more organic'' than products produced and handled in other States or under NOP requirements. Rather, the Secretary will approve only those State programs that need more restrictive requirements to protect or preserve unique environmental conditions or to accommodate product and handling practices unique to a State or portion of a State. In the absence of such environmental conditions or production practice needs, a State's organic program must have the same requirements as this NOP. If this is the case and if a relatively few State programs are approved to have more restrictive requirements, then no real purpose is served by permitting State organic programs to display a separate and distinct seal on a product label. Such a seal would not represent a ''more organic'' product.

In the place of a State organic program seal, this proposal provides for the seal or logo of a State certifying agent to be displayed on packages, if that certifying agent certifies the organic operation producing the product. Selection of a State or private certifying agent is the choice of the organic producer or handler being certified. A State's department of agriculture (or other equivalent State agency) may establish one or more State certifying agent offices as part of its governmental operations, or the State may license a private certifying agent to certify organic operations on behalf of the State. In either case, the certifying agent would certify these national requirements and not the particular requirements of a State organic program unless those requirements were approved by the Secretary. Therefore, the only organic seal or mark representing a State will be the seal or mark of a State's certifying agent or licensed certifying agent. Any certifying agent licensed by the State must be accredited by the Secretary pursuant to subpart F of this proposal.

(2) *Labeling for international markets.* We have added two paragraphs under section 205.300 to provide for labeling of products intended for international markets. Domestically produced organic products intended for export may be labeled to meet the requirements of the country of destination or any labeling